EXAMINING FEDERAL REGULATION OF MOBILE MEDICAL APPS AND OTHER HEALTH SOFTWARE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

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SUBMITTED MATERIAL

EXAMINING FEDERAL REGULATION OF MOBILE MEDICAL APPS AND OTHER HEALTH SOFTWARE

TUESDAY, NOVEMBER 19, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:01 p.m., in room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Present: Representatives Pitts, Burgess, Blackburn, Gingrey, Lance, Guthrie, Griffith, Bilirakis, Ellmers, Pallone, Capps, Matheson, Green, Butterfield, Barrow, Christensen, Castor, Sarbanes, and Waxman (ex officio).

Staff Present: Clay Alspach, Counsel, Health; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Oversight; Ziky Ablalya, Minority Staff Assistant; Eric Flamm, Minority FDA Detailee; Elizabeth Letter, Minority Assistant Press Secretary; Karen Nelson, Minority Deputy Committee Staff Director For Health; and Rachel Sher, Minority Senior Counsel.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The subcommittee will come to order. The chair will recognize himself for an opening statement. In the last few years, health information technologies including mobile medical apps, or applications, electronic health records, personal health records, computerized health care provider order entry systems, and clinical decisions support have transformed the provision of health care in this country.

In September of this year, the FDA put forward a proposal in the form of final guidance indicating that software was a medical device for the purposes of regulation, except that software is not a medical device. To regulate it as such, the FDA has said it will use discretion to decide which software to regulate. Except that no matter what Dr. Shuren may tell this committee here today, there is

no guarantee that its successor won't go back on this guidance tomorrow.

While guidance is a valuable tool for the FDA, there is a significant limitation, certainty. What stands today could change tomorrow. Patients and industry have told us that the FDA's involvement and guidance was a good thing. There was much too much ambiguity around the issue and companies needed to know what the FDA intended to do. In addition, many believe the FDA acted to the best of its ability with the only tool available to them: its medical device definition. But they also are telling Congress that we need to give FDA new tools that create regulatory certainty, not just today, but also tomorrow. That certainty can start with properly defining what these technologies are for the purposes of regulation.

Representative Blackburn and her colleagues on both sides of the aisle have outlined an approach that would give the FDA a new tool, a 21st century definition to regulate a 21st century technology. The SOFTWARE Act is a starting place and an opportunity to begin a dialogue with thought leaders like the FDA. Representative Blackburn and five of her colleagues, Democrats and Republicans, have put forward one way to modernize the FDA so that it is ready to meet the challenge it has so far recognized it needs to meet.

I commend her in her thoughtful approach to this issue, and for her leadership. Dr. Shuren, I stand ready to pledge this committee's support to help you modernize the agency in a way that makes sense for patients, for industry, and for the agency. And I hope you take this offer seriously, and will agree to work with us toward a goal we all share.

And to all of the witnesses on both panels here today, I thank you for your testimony. And I yield the balance of my time to the gentleman from Illinois, Mr. Shimkus.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

In the last few years, health information technologies, including mobile medical applications (apps), electronic health records, personal health records, computerized health care provider order entry systems, and clinical decision support, have transformed the provision of health care in this country.

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Dr. Shuren, I stand ready to pledge this Committee's support to help you modernize the agency in a way that makes sense for patients, for industry, and for the Agency. I hope you take this offer seriously, and will agree to work with us toward a goal we all share.

To all of the witnesses here today, thank you for your testimony and for being here today.

Thank you, and I yield the remainder of my time to Rep. _____.

Mr. SHIMKUS. Thank you, Mr. Chairman. I applaud the calling of this hearing and I, too, want to mention Congressman Blackburn and her bill. I am not a sponsor yet but we are looking at it seriously. It is bipartisan, and the issues we need to—we need a new tool to help us continue to modernize. Software is not a medical device, and what you call something matters, especially as we have our tech companies trying to go through a process. So I wanted to use this time to thank my colleague for her work. I look forward to you coming back, Dr. Shuren, and discussing how we can maybe give you some help and some tools so that we can label devices, devices, and label software, software. With that, Mr. Chairman, I thank you. I yield back.

Mr. PITTS. The chair thanks the gentleman. I now recognize the ranking member of the subcommittee, Mr. Pallone, for 5-minute opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman. The possibilities for mobile health technologies are promising and exciting and there are so many functions that mobile health applications can be designed for, from diet logs and medication reminders, to medical textbooks reference tools to ECG monitors, and they play an increasingly important role in getting health information into the hands of consumers and helping patients take control of their health. They may also help doctors improve and facilitate patient care by, for example, providing instant mobile access to standards of care, or helping to streamline their business processes.

I think it is fair to say that we all want to encourage continued innovation, but it is also important that we shepherd these emerging technologies and make sure that they are safe and effective for patients. As with traditional medical devices, some mobile apps that operate in the health sphere could pose a risk to patient safety if they don't work as they are supposed to, and we want to make sure consumers can have confidence in the products they use. When we last had a hearing 6 months ago on health information technologies, we heard from stakeholders a desire for clarity on

FDA's regulatory approach to mobile health applications and support for risk-based strategy that protects patients, ensures product quality, and at the same time, fosters innovation. The FDA has since finalized its guidance and laid out examples of the types of mobile applications, what it calls mobile medical applications that the agency will apply its regulatory authority to.

To me, and from what I have heard from industry, FDA's guidance is very measured and risk-based. We had heard concerns before the final guidance was out that FDA was going to regulate smartphones and tablets as medical devices and stifle innovations through regulation. In fact, as we see now, FDA's guidance clearly states that it would not regulate the sale or general use of smartphones or tablets and will not consider the manufactures of these products to be medical device manufacturers. Rather, the agency directs its oversight to those apps that are medical devices, as defined in existing statutes, and that could pose a risk to patient safety.

For certain mobile apps such as those that purport to diagnose cancer or that recommend a dosage plan for radiation therapy, there should be a role for FDA to play to ensure they are safe and effective. And these are the kinds of apps FDA has said it will direct its oversight to. I appreciate that we have the opportunity today to discuss the SOFTWARE Act, a bill introduced by my colleagues on our committee, Ms. Blackburn, Mr. Green, Ms. DeGette, Mr. Butterfield, and Mr. Gingrey. However, I have several concerns about this bill starting with the timing. FDA's guidance was released barely 2 months ago, and we have not had the opportunity to see how it works in practice, or to hear from industry whether it poses any barriers to innovation.

In addition, a small but important provision was passed as part of the user fee law last summer which required FDA, along with other Federal agencies, to recommend an appropriate regulatory framework that ensures patient safety, but also promotes innovation. These recommendations are not due until January of 2014. And I think it would be prudent for this committee to analyze and examine that report before moving any legislation.

And that leads to my second concern, which is whether legislation is even necessary and whether it is the right approach to take. As we all know, the legislative process is slow, and in an environment where technologies are changing so rapidly, I question whether it makes sense to enshrine in statute something that may not work for an ever-evolving industry. Regarding the content of the bill itself, I also have concerns about what it seeks to achieve, whether it meets those goals as written, and what the consequences down the road would be if we were to permanently carve out certain types of mobile health apps from FDA's oversight.

So in closing, I look forward to learning more today about FDA's regulatory approach to mobile health apps and the potential impact of the SOFTWARE Act. And again, thank you, and of course, I thank Dr. Shuren for being here.

Mr. Green, I will yield the remainder of the time to my colleague from Texas.

Mr. GREEN. Thank you, Ranking Member Pallone, for yielding time and I appreciate the majority holding the hearing on the

SOFTWARE Act which I cosponsored. I understand that there are concerns, but this proposal is a work in progress. It is important that we take time to get this right. A few weeks ago the FDA issued guidance on mobile medical apps and other software and I commend them for their thoughtfulness and leadership. Medical software and other health-related software is a quickly growing sector with unbelievable potential. The FDA has done all it can through enforcement discretion to implement commonsense steps to foster innovation and protect patient safety. Enforcement discretion is not the right tool, but it is all they have. It is Congress' obligation to give the FDA the tools necessary to properly protect patient safety, and also to encourage innovation and create regulatory certainty. That is why the SOFTWARE Act is important, and it is a work in progress.

And I guess this is the first time the Senate passed our compounding bill, and we learned with our effort on compounding that the FDA didn't have the authority or didn't think they had the authority, so we needed to deal with that. And I would hope we could get in front of the curve on software instead of behind the curve like we were on compounding. And I yield back my time.

Mr. PITTS. The chair thanks the gentleman. I now recognize the gentlelady from Tennessee, Ms. Blackburn 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. I think it goes without saying that I am very pleased that we are holding the hearing today. Tennessee is home to hundreds of health IT innovators and they are grateful that we are turning our attention to this issue. They feel like it is needed and so, Dr. Shuren, I thank you for being with us. To the other witnesses that we have today, we welcome you. We look forward to hearing from you, and I do want to thank my colleagues here on the committee, Dr. Gingrey, Mr. Green, Mr. Butterfield, of course, Ms. DeGette, who have worked on the legislation. We appreciate the efforts that they have put into this.

The health informatics industry is innovating at a pace that I think is startling to everyone who is watching. I am constantly amazed as I visit with these innovators and hear of their plans, and look at their research, and view the platforms that they are working with. Every day the use of technology becomes more engrained in how health care is delivered in the U.S. As such, Congress has a very important role to play to ensure that our agencies tasked with ensuring the safety and efficacy of these technologies has the proper tools necessary to do the job to understand their mission, and not to overstep.

Unfortunately, the FDA is stuck trying to use a 1970s definition of a medical device to regulate mobile medical apps and other health care-related software. We can all agree that there is certainly a role for the FDA to play as we go about determining the regulatory playing field for this growing sector and trying to funnel

these products into existing outdated definitions is just not going to make any sense and it will not work.

The SOFTWARE Act would give the agency a needed tool for emerging technologies where necessary, while allowing moderate to low risk technology developers the certainty necessary to proceed with development, knowing full well what the regulatory playing field is going to be.

It would provide certainty for our innovators who are constantly working to deliver health care in a more efficient manner. With their decisions and the September 2013 mobile apps guidance to use, enforcement discretion to regulate only a subset of mobile medical apps, the FDA took an important step to acknowledge where their focus should be. Congress has the opportunity to go a bit further and codify this intent to ensure that our innovators have the clarity and certainty they need to continue to invest in this area, and develop tools that will help make us healthier.

At this time, I yield the balance of my time to Dr. Burgess, vice chair of the subcommittee.

Mr. BURGESS. I thank the vice chair for yielding, and Dr. Shuren thank you for being here. It is always good to see you in our subcommittee. Don't make yourself so scarce now that you know where we are.

I do want to emphasize the point that providing that certainty for software developers, providing clarity for industry is one of the things that we seek to accomplish today. We want predictability for our providers. There are areas of, emerging area of clinical decision support has the ability to transform practice of medicine in the realm of continuing medical education, always a challenge for clinicians to meet the requirements that are imposed, generally at a State level, but now you also have the new Sunshine Laws that perhaps may make it harder to keep up with these programs that otherwise we would have the ability to support our doctors.

The issue is that the lack of careful regulation could end many of these programs before they even begin, and it is a bright future ahead of us, and we want to be certain we do everything to provide that predictability and clarity for our providers and for industry alike. And I yield back the balance of my time.

Mr. PITTS. The chair thanks the gentleman. And now recognize the ranking member of the full committee, Mr. Waxman, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. Mobile medical applications hold incredible promise for patients and health care provider, potentially reducing cost, improving health care delivery, and saving lives. We should all want to see this exciting innovation continue. At the same time, we must be cognizant of the need to protect patient safety, so just as we do when it comes to all types of medical devices, we logically look to the FDA to oversee the safety of these cutting-edge technologies. FDA has been regulating software under its medical device regulatory scheme for decades. At the end of September FDA issued final guidance regarding

mobile medical applications, and I think it struck the right balance. It ensures that patients are not placed in harm's way by these medical apps, and they do not apply undue regulatory restraints in the way of innovation.

As the FDA says in its guidance something like a dietary tracking app which reminds you of a medical appointment, or some dietary information, help you follow a diet. That kind of app purports to—that kind of app is certainly one that we don't want FDA to regulate. But an app that tells you whether you have cancer or not, well, that deserves a lot of scrutiny.

Because let me give you an example. A group of dermatologists recently published a study of four apps that claim to be able to diagnose melanomas. That is a very serious skin cancer. The dermatologists found that three of the four apps incorrectly classified 30 percent or more of melanomas as benign when they were actually malignant. Well, that is a kind of device where you want FDA to take a look at. We don't want you to just say you don't have to be involved, FDA, we are going to let people get access to it. We can't tell the American people buyer beware when potentially life and death care decisions are at stake.

FDA's final guidance should put to rest any concerns that this agency is interested in a regulatory overreach now or in the future. FDA, very reasonably and clearly, sets forth the types of mobile medical applications that the agency intends to oversee, as well as those it does not. For instance, FDA's guidance says that it intends to look at only those apps that could impact patients' safety. At the same time, the guidance specifically states that the agency does not intend to regulate distributors of mobile medical apps like iTunes store or the makers of smartphones or tablets like Apple.

Today we have before us a bill. It is called the SOFTWARE Act and it attempts to codify, put in law some of what FDA has set forth in this guidance. And I appreciate the offer of the sponsors of this bill to work on that legislation, and talk more about it. But I am skeptical of the need for legislation in this area at this point in time for a number of reasons.

First of all, FDA's guidance was just issued at the end of September. We barely had an opportunity to see how it is working out, whether there are instances of burdensome requirements stifling innovation in this area. It is not appropriate to legislate based on unfounded fears of what might happen in the future.

Second, by almost all of the accounts I have heard, the guidance has been favorably received by most of the industry. It is written in a clear and concise manner, including a litany of specific examples that provide the regulatory certainty so many in the industry were seeking.

And third, as I mentioned, FDA's guidance strikes the right balance between protecting patient safety on the one hand, and promoting innovation on the other. As I think we will hear today, the current draft of the SOFTWARE Act does not strike that balance. This bill upsets that balance. I think there are several examples of mobile medical apps that I think we all would agree should not be permanently removed from FDA's oversight, but that is exactly what the current draft does.

I am not suggesting this was the intent of the sponsors, but it does illustrate a major concern I have whether the blunt instrument of legislation is the appropriate tool for regulation of mobile medical apps given the rapidly changing nature of technology in this area. As we all know, once the law is in place, it is very difficult to change it, and it is exceedingly difficult to craft the perfect legislative language that would preserve FDA's ability to oversee appropriate subsets of these changing technologies now and in the years in the future. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman. That concludes the opening statements of the members. We have two panels today. On our first panel we have Dr. Jeffrey Shuren, director of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. Thank you for coming today, Dr. Shuren. Your written testimony will be entered into the record. You will have 5 minutes to summarize your testimony. And at this time, you are recognized for 5 minutes.

STATEMENT OF JEFFREY E. SHUREN, M.D., J.D., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, UNITED STATES FOOD AND DRUG ADMINISTRATION

Dr. SHUREN. Thank you, Mr. Chairman, and members of the subcommittee for the opportunity to testify today. The use of mobile apps is revolutionizing health care delivery and has the potential for transforming health care by allowing doctors to diagnose patients outside of traditional health care settings, and help consumers manage their own health and wellness. We are excited about these technologies, and have been taking steps to facilitate their development and safe use. Developers of mobile apps have been asking for guidance about which mobile apps are subject to FDA oversight and not. Such clarity is critical for tracking investment in accelerating innovation.

Recently we provided that clarity by issuing final guidance. The gist of that guidance is the following: Although many mobile apps pertain to health, of which many may be medical devices we are only overseeing a very small subset of those mobile apps that are medical devices. We have called that subset mobile medical apps. We believe this pragmatic, narrowly-tailored approach will promote innovation while protecting patient safety by focusing on those mobile apps that pose greater risks to patients. Our regulation of software as a medical device, and a mobile app is software, is based on risk and function, their intended use. A foundational principle is that we treat devices that perform the same function for a patient the same regardless of the platform on which it is used.

For example, an electrocardiography device, an ECG machine that measures heart rhythms to help doctors diagnose patients, is still an ECG machine regardless of whether it is the size of a bread box or the size of a smartphone. The risk it poses to patients and the importance of assuring for practitioners and patients that it is safe and effective is essentially the same. That is what our guidance does. It makes clear that if a mobile app is a medical device, specifically, it transforms a mobile platform into a medical device, like an ECG machine, and we have cleared apps for that, or it is an accessory to a medical device, such as an app that acts as a re-

mote control for a CAT scanner and is the kind of function we already regulate so we have approved it, cleared it, or classified such a device, we would continue to regulate that kind of technology if it is on a mobile platform rather than on a non-mobile platform. A mobile medical app is simply a mobile app that is a medical device and a kind of device we have approved cleared or classified.

Again, it is not about the platform. It is about the function. An ECG is an ECG. And regulating mobile apps is nothing new for us. In the past 15 years, we have cleared over 75 mobile apps, roughly 20 in the past year. For all other types of mobile apps that meet the regulatory definition of medical device, we will exercise a policy known as enforcement discretion. This means we do not intend to enforce requirements under the law. In addition, we will exercise enforcement discretion for some functions we have been actively regulating; for example, medication reminders, and drug-drug interactions.

Taken together, we have focused our priorities and taken a big deregulatory action, the biggest we have taken in over a decade. We received about 130 comments in a draft guidance, which were generally supportive of the approach we propose, but wanted even more clarity; therefore, the final guidance keeps the same core policy, but provides clearer explanations and more examples. Also, we clarify that at the request of some of our stakeholders, this guidance does not apply to what has been called clinical decision support software; software to aid a practitioner or patient in making a decision.

Instead, we have been asked to and will address clinical decision support software as part of the ongoing effort we have with the Office of the National Coordinator of Health Information Technology, and the FCC, to post a proposed strategy and recommendations on a risk-based regulatory framework pertaining to health IT as required by FDASIA. As part of this effort, we established a multistakeholder working group to provide us some recommendations on what to consider when proposing a framework. The working group gave their final recommendations in September. They recommended the FDA explain which forms of clinical decision support software it regulates. They also highlighted the importance of treating function the same across platforms, what we are doing, and recommended that we expedite our guidance on mobile medical apps because of its critical importance in providing clarity.

We will provide ongoing clarity to mobile app providers through a new Web site to which we will continually pose new examples of apps that we are not actively regulating. App developers who have questions can contact us through several means, including a new email address. Queries will be handled by a special team under the guidance of CDRH senior managers. Smart regulation by FDA can help promote innovation in mobile apps, and protect patient safety.

Mr. Chairman, I thank the subcommittee for its efforts. I am pleased to answer any questions you may have.

[The prepared statement of Dr. Shuren follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

JEFFREY SHUREN, M.D., J.D.
DIRECTOR
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"EXAMINING FEDERAL REGULATION OF MOBILE MEDICAL APPS AND OTHER HEALTH SOFTWARE"

NOVEMBER 19, 2013

Release Only On Delivery

INTRODUCTION

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee, I am Jeffrey Shuren, Director, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I am pleased to be here today to discuss FDA's recently published final guidance, "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff"[1] and, more specifically, the actions FDA is taking to protect the public health and foster innovation in the field of mobile applications (mobile apps). This final guidance was long awaited by developers of mobile medical apps and will provide clarity regarding which mobile apps are the focus of FDA oversight and which are not. Mobile health app developers and manufacturers needed a clear, predictable, and reasonable understanding of the Agency's expectations. Such clarity is critical for attracting investment and accelerating innovation. As our final guidance demonstrates, FDA has adopted a balanced approach to mobile apps that supports continued innovation while ensuring appropriate patient protections. The Agency intends to exercise enforcement discretion for the majority of mobile apps that are devices as they pose minimal risk to consumers. FDA intends to focus its regulatory oversight on a subset of mobile apps that present a greater risk to patients if they do not work as intended.

The widespread adoption and use of mobile technologies is opening new and innovative ways to improve health and health care delivery. Mobile apps—software programs that run on smartphones and other mobile communications devices—can help consumers, health care professionals, and patients manage health and wellness, promote healthy living, and gain access

[1] FDA, "Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff" (Sept. 25, 2013), available at *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263366.pdf.*

to useful information when and where they need it. Not surprisingly, these tools are being adopted almost as quickly as they can be developed. In fact, industry estimates that 500 million smartphone users worldwide will be using a health care application by 2015,[2] and by 2018, 50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications.[3]

Mobile apps span a wide range of health functions. While many mobile apps carry minimal or no risk to patients, a small subset of these apps can pose significant risks to patients if they don't operate correctly. And, as we will discuss, FDA's final guidance takes this variation in risk into account.

In some cases, the risks associated with mobile apps are similar or identical to the risks associated with an already-marketed medical device. As an example, mobile apps that affect the programming of a drug infusion pump or computed tomography scanner could lead to a drug or radiation overdose. An inaccurate or malfunctioning mobile medical app that uses a sensor to diagnose skin cancer or to measure critically low blood oxygen levels in chronic lung disease patients, could delay lifesaving diagnosis and treatment.

It is important to note that FDA has been regulating medical device software for decades and medical device software on mobile platforms for more than 10 years. The Agency has reviewed approximately 100 mobile medical apps, including remote blood pressure, heart rhythm, and patient monitors, and smartphone-based ultrasounds, ECG machines, and glucose monitors.

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[2] Research2Guidance, "500m people will be using healthcare mobile applications in 2015" (Nov. 10, 2010), available at *http://www.research2guidance.com/500m-people-will-be-using-healthcare-mobile-applications-in-2015/*.

[3] Research2Guidance, "Mobile Health Market Report 2013-2017: The Commercialization of mHealth Applications" (March 4, 2013), available at *http://www.research2guidance.com/shop/index.php/downloadable/download/sample/sample_id/262/*.

Development of FDA's Mobile App Guidance

FDA has jurisdiction over those mobile apps that meet the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). As you know, FDA issued draft guidance in July 2011 to announce its intention to exercise enforcement discretion for most mobile apps. The guidance also clarified that the focus of FDA's oversight will be the small subset of mobile apps, referred to as "mobile medical apps," that meet the definition of "device" in section 201(h) of the FD&C Act and that are either intended to: (1) be used as an accessory to a regulated medical device[4] or (2) transform a mobile platform into a regulated medical device.[5] This narrowly tailored approach will not require active FDA oversight of many apps that would otherwise meet the definition of "device."

Throughout the development of the mobile medical apps guidance, FDA has actively encouraged public feedback on how its regulatory approach would affect the balance between promoting innovation and providing reasonable assurance of safety and effectiveness. In addition to opening the draft guidance for public comment, the Agency interacted with the stakeholder community, including traditional medical device firms, software companies, health care professionals, patient advocacy groups, health care facilities, third-party payers, and the health information technology (IT) community. FDA also hosted a widely attended public meeting to provide a forum for discussion and to encourage additional public comment from interested stakeholders on the issues raised in the draft guidance.[6]

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[4] For example, an application that allows a health care professional to make a specific diagnosis by viewing a medical image from a picture archiving and communication system (PACS) on a smartphone or a mobile tablet.
[5] For example, an application that turns a smartphone into an ECG machine to detect abnormal heart rhythms or to determine if a patient is experiencing a heart attack.
[6] FDA, "Public Workshop - Mobile Medical Applications Draft Guidance, September 12-13, 2011," available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm.*

FDA received more than 130 submissions to the public docket on the July 2011 draft guidance. Respondents overwhelmingly supported a narrowly tailored, risk-based approach, and industry stakeholders were eager to see the guidance finalized. On September 25, 2013, FDA announced the publication of the final Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff in the *Federal Register*.[7]

Our mobile medical app policy is based on risk and functionality. For example, an electrocardiography device—an ECG machine—that measures heart rhythms to help doctors diagnose patients is still an ECG machine, regardless of whether it is the size of a bread box or the size of a credit card. The risks it poses to patients and the importance of ensuring for practitioners and patients that it is safe and effective are essentially the same. Our guidance makes clear that if a mobile app transforms a mobile platform into a medical device, like an ECG machine, or is an accessory to a medical device, such as an app that acts as a remote control for a CT scanner, and it is the kind of functionality we already regulate—that is, we have approved, cleared, or classified such a device—we would continue to regulate that kind of technology, if it is on a mobile platform.

Just as important as what the policy does is what the policy does not do. FDA's mobile medical apps policy will not result in the regulation of the sale or general consumer use of smartphones or tablets. FDA's mobile medical apps policy will not result in the consideration of entities that exclusively distribute mobile medical apps, such as the owners and operators of the "iTunes App store" or the "Android market," as medical device manufacturers. FDA's mobile medical apps policy will not result in the consideration of mobile platform manufacturers as medical device

[7] FDA, "Mobile Medical Applications; Guidance for Industry and Food and Drug Administration Staff; Availability," 78 *Fed. Reg.* 59038 (Sept. 25, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-25/pdf/2013-23293.pdf.*

manufacturers just because their mobile platform could be used to run a mobile medical app regulated by FDA. FDA's mobile medical apps policy will not result in mobile medical app developers having to seek Agency re-evaluation for minor, iterative product changes.

The guidance also states the Agency's intent to exercise enforcement discretion for those mobile apps that meet the FD&C Act's definition of a "device" but do not meet the definition of a "mobile medical app" in the guidance. Mobile apps that may be considered devices for which we would exercise such enforcement discretion and not enforce requirements under the FD&C Act include mobile apps that:

- Help patients self-manage their diseases or conditions without providing specific treatment suggestions;
- Provide patients with simple tools to organize and track their health information, such as blood pressure and drug intake;
- Provide patients with easy access to information related to their health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to health care practitioners;
- Provide or facilitate supplemental care, by coaching or prompting, to help patients manage their health—such as weight maintenance apps;
- Enable patients or practitioners to interact with Personal Health Records or Electronic Health Record systems;
- Help patients maintain a healthy weight, manage salt intake, adhere to drug intake times, and prevent drug-drug interactions;
- Supplement a verbal discussion with a patient's health care practitioner, using a camera or videoconferencing portal;

- Conduct simple calculations, such as Body Mass Index, APGAR[8] scores, delivery date estimators, or mean arterial pressure; or
- Provide reminders (for example, medication reminders—mobile apps that provide alerts to patients or health care providers for pre-determined medication dosing schedules).[9]

FDA developed the Agency's mobile medical apps policy to protect public health and promote innovation. Because the final guidance states that the Agency intends to exercise enforcement discretion for certain categories of mobile apps with respect to applicable device requirements, including listing,[10] FDA does not expect such devices to be listed. The guidance provides clarity regarding the specific types of apps for which the Agency intends to exercise enforcement discretion in the final mobile medical apps guidance.

Due to the tremendous interest in the final guidance, FDA conducted significant communications outreach to our Federal partners, including the Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONC), Federal Communications Commission (FCC), Federal Trade Commission (FTC), and Congress; industry, patient, and consumer groups, and other stakeholders; specialty mobile app bloggers; mobile app publications; and traditional news media. In addition, we participated in a panel

[8] APGAR is a quick test performed on a baby at one and five minutes after birth to determine how well the baby tolerated the birthing process and is doing outside the mother's womb. For more information, please see *http://www.nlm.nih.gov/medlineplus/ency/article/003402.htm*.

[9] Certain mobile apps are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health, or wellness. When these items are not marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or do not otherwise meet the definition of medical device, FDA does not regulate them. When they are marketed, promoted, or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or otherwise meet the definition of medical device, FDA intends to exercise enforcement discretion.

[10] Owners or operators of places of business involved in the production and distribution of medical devices intended for use in the United States are required to register annually with FDA, known as establishment registration. Most covered establishments are also required to list the devices made there and the activities performed on those devices. For more information, see FDA, "Device Registration and Listing," available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/registrationandlisting/default.htm*.

discussion sponsored by the Congressional Medical Technology Caucus, which many of your staff attended. We have established a publicly available website[11] with up-to-date information, listing those apps which have been cleared or approved by FDA and those for which FDA intends to exercise enforcement discretion, in order to provide continuing clarity on this issue for industry and other stakeholders. Mobile app developers who have questions can contact us through several mechanisms, including a new e-mail address.[12] Queries will be handled by a special team under the guidance of CDRH senior managers. Also, in response to queries, we will continually update our website, as appropriate, to include additional examples of apps for which we intend to exercise enforcement discretion.

Developing an Appropriate Risk-based Regulatory Framework for Health IT

Mobile medical apps represent just one component in an increasingly connected health care environment. Three Federal Agencies—FDA, ONC, and FCC—have unique and complementary responsibilities in the health IT arena. Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA),[13] enacted on July 9, 2012, requires the Secretary of HHS, acting through the Commissioner of Food and Drugs and in consultation with the National Coordinator for Health IT and the Chairman of FCC, to prepare a report by January 2014 containing "a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[14]

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[11] See FDA, "Mobile Medical Apps," at *http://www.fda.gov/medicaldevices/productsandmedicalprocedures/connectedhealth/mobilemedicalapplications/default.htm*.

[12] The e-mail address is *mobilemedicalapps@fda.hhs.gov*.

[13] Food and Drug Administration Safety and Innovation Act, Public Law 112-144 (126 Stat. 993) (July 9, 2012), available at *http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf*.

[14] *Id.*

FDA, ONC, and FCC established a "FDASIA Workgroup" under ONC's Health Information Technology Policy Committee (HITPC),[15] which provided expert input to HITPC to inform the development of this report. The FDASIA Workgroup was comprised of a wide range of stakeholders and conducted in a transparent manner with ample opportunity for public comment. The workgroup gave its final recommendations in early September 2013, which the Committee adopted. Of note, the multi-stakeholder workgroup highlighted the importance of treating functionality the same across platforms and recommended that FDA expedite guidance on mobile medical apps because of the critical importance of providing clarity as soon as possible.

CONCLUSION

FDA recognizes the importance of implementing a balanced, transparent approach that fosters the development of health IT solutions and innovative products like mobile medical apps, while ensuring appropriate patient protections. Like traditional medical devices, mobile medical apps may in some cases present significant health risks to patients if they do not work as intended. FDA seeks to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile apps that present risks to patients if they do not work as intended. As explained in the medical mobile apps guidance, FDA will not regulate the sale or general consumer use of smartphones or tablets.

In its regulation of medical devices, the Agency strives for transparency, interaction, collaboration, and the appropriate balancing of benefits and risks; ensuring predictable and

[15] *See* FCC, "Membership Applications Sought for FDA Safety Innovation Act Workgroup," available at *http://www.fcc.gov/membership-applications-sought-fda-safety-innovation-act-workgroup*. The Workgroup was formed under the ONC's HITPC, a Federal advisory committee established by the Health Information Technology for Economic and Clinical Health (HITECH) Act (Title XIII of the American Recovery and Reinvestment Act, Public Law 111-5 (123 Stat. 115) (Feb. 17, 2009) (available at *http://www.gpo.gov/fdsys/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf*).

consistent recommendations, decision-making, and application of the least-burdensome principle; and implementing efficient processes and use of resources. FDA's guidance on mobile medical apps, and the tri-Agency collaborative effort on health IT, reflect this regulatory approach.

Thank you for your commitment to the mission of FDA and our medical device program, which helps to ensure that patients and health care professionals have access to safe and effective innovative medical technologies. Thank you for the opportunity to testify today about FDA's mobile app guidance and about the actions that FDA is taking to foster innovation. I am happy to answer questions you may have.

Mr. PITTS. The chair thanks the gentleman, and we will now begin questioning. I will recognize myself 5 minutes for that purpose.

Dr. Shuren, the FDASIA working group produced a report on the issue of regulation of mobile medical apps and other software. Included in the FDASIA report are problems associated with the challenges faced by FDA related to wellness and disease, accessory issues, post-market requirements for networks, enforcement, interoperability of medical devices, regulatory jurisdiction on converged medical devices, and resource constraints among other issues. Is that correct?

Dr. SHUREN. Yes, they did make recommendations pertaining to all of those.

Mr. PITTS. And isn't it true that the FDASIA working group stated there are issues in each area that I just mentioned that are "broken at the written law level."

Dr. SHUREN. They did say that. In reality, from our perspective many of the things we need to do are about providing clarity in those areas, which is something we intend to do.

Mr. PITTS. Now, Dr. Shuren, as the opening statements here today suggest, and in light of reports like the FDASIA working group report, there is a strong role for Congress to modernize the FDA to regulate software and other forms of health information technology because the written law is antiquated and did not take into account such technologies when it was written 30 years ago. Understanding this, did your office reach out to my office or other offices of members on the health subcommittee with an offer to work together on this issue before you released the proposed or final guidance?

Dr. SHUREN. Not to my understanding, but we have certainly gotten lots of input from the stakeholder committee. It is something we have been working on for roughly 2 years.

Mr. PITTS. Can you tell me why your office did not reach out to offer collaboration on this issue when you knew the important role Congress needs to play in this space?

Dr. SHUREN. I think in this space we were trying to provide clarity regarding our current authorities, which is what we did. I will tell you that if we certainly felt that at the time there was a need for legislation, we would absolutely have reached out to you, and you have had hearings on this matter before, and we have stated the same previously. But we certainly welcome opportunities to work with you, and I will say it is Congress' prerogative to pass legislation. That is certainly your choice to make. We would hope, though, that we have an opportunity to engage and certainly point out implications of any legislative path that may be under consideration.

Mr. PITTS. Now, Dr. Shuren, you have publicly intimated in the past that the FDA could regulate electronic health records as medical devices. Can the FDA regulate electronic health records as medical devices?

Dr. SHUREN. Arguably, yes, but we have stated on the record and we have put into formal policy that that is not what we are doing. And that is now official policy of the agency.

Mr. PITTS. Now, in her testimony on behalf of the FDA to this committee on March 21st, 2013. Christy Foreman said that the FDA could change its mind tomorrow and regulate items and products not described in its final guidance, products like electronic health records, or clinical decision support programs.

Dr. Shuren, do you agree with Christy Foreman that the FDA could change its mind and regulate beyond the FDA guidance it published in September 2013?

Dr. SHUREN. So I don't know what Christy actually said, but we have now put in place a final policy. I can't change that overnight. There are statutory requirements that we have to comply with to change any such policy which requires extensive public input on proposal, and there is congressional oversight. Changing policies like that, if there is disagreement within the community, is exceptionally difficult to do.

The value, though, of such policies and guidance, and I will tell you that we have had extensive conversations during FDASIA about the invaluable nature of guidances to provide both predictability, and flexibility, both are critical to industry, particularly an industry like health care IT that is rapidly innovating. So our guidance, we spent 2 years with extensive input with a public meeting, a proposal, public comment, then final guidance, and that is about 40 pages long with extensive explanations and examples, and answering questions. And it gives us the ability that if the health care IT community—and it gives them the flexibility that if they, over time, as their technologies evolve, they feel, you know what FDA, we want you to make certain changes, we have the ability to do that. The challenge with statute, and it is your call whether or not to do that, is to take what is a 40-page document, and hone it down into a few sentences of statute, is not only very challenging, it becomes difficult to make changes to because statute is so much inflexible compared to——

Mr. PITTS. My time is expired. I just want to clarify your answer. Can FDA change it, a guidance at any time—its guidance at any time?

Dr. SHUREN. Not overnight. Not overnight. We have to go through a long process.

Mr. PITTS. All right, the chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. I wanted to thank Dr. Shuren for being here again. As you know, Representative Blackburn has introduced a bill, H.R. 3303, that would create an entirely new regulatory framework for medical software. It creates three new categories, medical software, clinical software, and health software. The effect of the bill is to remove entirely from FDA's jurisdiction clinical and health software, and if I read the bill correctly, FDA could still regulate so-called medical software, but the bill says the medical software would no longer be considered a medical device even though FDA could continue to use all of its device authorities to regulate it.

Now, supporters of this bill assert that it is essentially an effort to codify FDA's mobile medical apps guidance. So I wanted to ask you briefly, is that what this bill does and do the two cover the same policies? Quickly, though, because I've got a lot of questions for you.

Dr. SHUREN. No, this doesn't codify our policy. It takes out from our authority the ability to assure the safety and effectiveness of devices that we currently regulate, including some high-risk devices.

Mr. PALLONE. All right. Now focusing on the medical software, it appears this category is intended to describe software that is marketed directly to consumers and would make clinical recommendations that could result in the consumer taking some health action in response to that recommendation, but without actually seeing a doctor. And that certainly is a type of software I would want FDA to look at too, but I am concerned about the way it is drafted and what the actual effect would be. So the question is, are there examples of software FDA currently regulates, or would be interested in overseeing, that would be excluded by this definition?

Dr. SHUREN. Yes. And our read of it, this is not just limited to software for consumers. So our read is we would no longer be able to assure safety and effectiveness of blood glucose meters, which measures sugar in the blood and is used by diabetic patients and doctors to determine if they need insulin and how much insulin. We have cleared an app for it. We wouldn't be able to assure the safety and effectiveness of software that is used to analyze the Pap smear slides, and highlight the fields that the health care provider should look at to then screen for cervical cancer. And if we can't assure it is accurate, then those providers may be missing cervical cancer.

Mr. PALLONE. All right, let me move on. I am also concerned about what the impact would be of giving this broad set of software a new definition and excluding it from the device definition. Is there any question, is there any precedent for that kind of legislation, and what would the effect of saying something is not a device but authorizing FDA to use all of its device regulatory authorities?

Dr. SHUREN. I am not aware, and I have asked my agency. We are not aware of any similar case. And it is very confusing to us what this actually accomplishes.

Mr. PALLONE. Yes, I would agree with that. Lastly, I am not going to have enough time to explore the other two categories in the bill with you, but hopefully somebody else will. But let me ask you a more general question. The reason we are even talking about legislation today on the heels of the release of FDA's guidance is that some are apparently concerned that the guidance leaves too much room for chance and it is unpredictable. But in the face of what I know is a rapidly changing marketplace, I am concerned about using legislation as a tool here at all.

So do you think it is appropriate to be looking at legislation at this point, and can you say anything to alleviate fears that FDA is going to stray far from this final guidance in the future and begin regulating every mobile app on the market? I think that is the concern.

Dr. SHUREN. Right. Like I said for legislation, it is your prerogative. We want to make sure you understand from our perspective the implications, at least for the bill as currently drafted. We think at the present time, it may be premature for legislation. If we are going to talk about things that suddenly are not regulated and go

into a new framework, what is that framework? What is being put in place? And once you draw lines, and it is chiseled in stone, we are sort of locked in for a long period of time. Are those the lines then on which you develop a framework around? Now, we are not saying there isn't going to be a need for legislation at some point. There may well be. But we think at the present time, this is just simply premature.

Mr. PALLONE. What about my last thing, Dr. Shuren, the fear that FDA is going to stray from its final guidance and regulate every mobile app?

Dr. SHUREN. Yes. No, we are not going to do that. There are a lot of hoops and hurdles for us if we ever go there, and quite frankly, let me put a sensitive topic on the table, laboratory developed tests, I think people know we have been trying to change an enforcement policy. While I have been at the agency we have been trying to change that policy for 15 years.

Mr. PALLONE. All right. I don't know if you answered my last question, but I guess that is the best I am going to get, right?

Dr. SHUREN. The answer is no, we are not going to be going after a whole bunch of other mobile apps.

Mr. PALLONE. All right, thank you Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentlelady from Tennessee, Ms. Blackburn, 5 minutes for questions.

Mrs. BLACKBURN. Thank you, Dr. Shuren, and we do appreciate that you are here, and look forward to working with you as we continue to go through this process. Let me stay with the framework, and of course, FDASIA requires your working group deliver a framework, regulatory framework, what it would look like, the various agencies, where the responsibility would lie, and when do you expect that we are going to be able to see that?

Dr. SHUREN. So I am expecting that it won't be our call to make because it will go through administration review. I think it is more reasonable to expect that more in the February time frame. But again, I am not the one to make that decision.

Mrs. BLACKBURN. Do you think we are safe saying first quarter next year?

Dr. SHUREN. Yes, I think that is realistic.

Mrs. BLACKBURN. OK, that is great. And then do you know what the report is expected to say about strengths and weaknesses of the FDA regulating in this space?

Dr. SHUREN. Excuse me, the report——

Mrs. BLACKBURN. You are excused.

Dr. SHUREN. Thank you. I had a teenage moment right there. The report isn't done so it is hard to comment on what is in there, but you can anticipate what we are focusing more on are the things where FDA isn't dealing with technologies than what is the framework that should be in place? And where are the areas where there are additional clarity between what the different agencies do? That is, and that should be in place. And I will tell you, the report will give thinking. It will give proposals. We will be seeking public comment on that before proceeding to even do anything on the framework. So that framework isn't going to say here is the proposed policy, give us comment, and we move to final. It is a step before even

getting to trying to put formal proposals in place for a framework. So there are lots of opportunity for input. In fact, we believe it is essential that we are working closely and collaboratively with the stakeholder community in trying to put in place what best meets the needs of the entire stakeholder community, the innovators, and patients, and practitioners.

Mrs. BLACKBURN. OK, do you think that your framework would require the FDA to modify its approach if it identifies FDA's—some regulatory weaknesses, we will say it like that, and then would you expect those changes to be big or small?

Dr. SHUREN. So right now there is nothing written in stone. What we will do is we will put out ideas. We will get feedback on that. Things may change based upon what we hear back from stakeholders as we move forward. And there are particular areas where there is still need for greater clarity that we are going to take the time and attention to work with stakeholders on what final policy should look like. We are not rushing to judgment. We think we need to give it the time and we need to give it the collaboration that is absolutely essential to try to get it right. But also, to give flexibility to this community, and allow the marketplace to evolve. What we worry about is locking ourselves into such a great degree, we end up stifling innovation because we really haven't thought through what will happen in the future. We don't know what is going to happen in the future. Do we have the flexibility to account for it as times change, and as technology evolved?

Mrs. BLACKBURN. I think that one thing we can all agree on is we do not want to stifle innovation, and I would appreciate if we can say that is a shared goal, and something that we would seek to do. For those of us that have rural areas that are dependent many times upon expanding access to certain health care concepts, this, the mobile medical apps plays a tremendously important position in that delivery.

So I like hearing you say let's not stifle innovation. I think that our community of innovators would appreciate hearing that also. I do think it is important that you conduct impact analysis, not only on the industry, but on patients, and as you all have worked through this process, are you conducting that type of impact analysis and looking at the expectation of what that innovation can have on the industry and on individuals, on patients?

Dr. SHUREN. So we certainly take into account what the impact when we are looking at regulating, or on the flip side I would say not regulating, particular technologies. We do take that into account. For the framework that everyone has been talking about that we need a new framework for some of these technologies, we are early on for kind of considering what does that look like, and what the impact will be, which is why we think it is so critical to have those collaborative efforts with the stakeholders, to figure out what to do and understand what the implications are.

Mrs. BLACKBURN. Thank you, I yield back.

Mr. PITTS. The chair thanks the gentlelady. I now recognize the ranking member of the full committee, Mr. Waxman, 5 minutes for questions.

Mr. WAXMAN. Thank you, Mr. Chairman, I want to follow up, Dr. Shuren, with the questions that Mr. Pallone asked you about the

effect of the SOFTWARE Act, the proposed bill, that proposed new law. I am still concerned about the notion that we could successfully use legislation to effectively give FDA the tools it needs to assure patient safety when they use these apps. You know, this is a balance. We don't want to stifle innovation but we don't want patient safety to be at risk. So let me ask you about the two categories that are defined in this bill. One says there is clinical software, and the other part of the bill says there is health software. The bill would completely remove FDA's jurisdiction to even look at both of these newly defined types of software.

Now, clinical software is clinical decision support software that captures, analyzes, changes, or presents patients or population clinical data, but does not directly change the structure or function of the body and is intended only for the use by health care providers. Health software is software that can also capture, analyze, change, or present patient or population clinical data. It can support administrative or operational aspects of health care, but is not used in the direct delivery of patient care. So that is what defined in the bill.

First, let me ask you an overarching question about both of these categories before I get into the specifics about each. Do you see any problems with your existing authority over the apps that these provisions would cover, such that there could be an advantage in putting them into a newly defined categories of unregulated products for which some future regulation would be contemplated?

Dr. SHUREN. We think one of the challenges with suddenly carving out areas, writing them down in statute for the moment, is that in trying to figure out what a new framework looks like, you are stuck with those definitions. You are stuck with those categories, and you have to build a framework around those, and it is unclear at this point if those lines are drawn in the best possible way for the most appropriate regulatory framework that facilitates innovation, while also protecting patients.

Mr. WAXMAN. Well, they define these categories and say you can't even look at them anymore. Let's look at this clinical software category. As I read it, it would seem to cover a large swath of software that the guidance that FDA issued specifically says warrants FDA oversight. For example, it seems to cover mobile apps that perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations.

I want to know if that is your interpretation. Are there examples of software that the bill would explicitly exempt FDA regulation, but that FDA believes raise patient safety issues warranting oversight?

Dr. SHUREN. Yes, it does. And some of those examples we included in our guidance. So for example, computer-assisted diagnostics, or computer-assisted detection devices analyze radiological images for highlighting what may be cancer so they can be used on mammograms to help a radiologist determine if there is cancer or not. And if it is inaccurate, if don't make sure it is safe and effective, radiologists may miss cancers or they may send women for inappropriate biopsies.

Radiation therapy planning which takes patient information and analyzes their imagining studies to come up with what dose of ra-

diation should be given for their cancer. Very complicated analysis that usually took weeks, several experts, including a physicist, now done by software, and then that is uploaded to a machine that can deliver the radiation. If that is not safe and effective, then cancer patients don't get the right radiation to their cancer, or they get radiation to their healthy tissue.

Mr. WAXMAN. Let me ask you because I have a limited time. There is a category called health software. This seems aimed at excluding software such as electronic health records, which the FDA guidance already describes is not warranting oversight. Let's assume we all agree that FDA should not have authority over electronic health records. But putting aside for a moment whether you think that is a good or bad idea, could you describe the factors one would have to take into account so as not to inadvertently capture things that truly warrant FDA oversight because of patient safety concerns?

Dr. SHUREN. Well, certainly in any category, let's say we do talk about electronic health records, I will put it on the table. You have to be very clear about what are we talking about? Are we talking about electronic version of medical records, or are we talking about more, because software is software. You can combine function in a variety of different functions, so can you take what you could call an electronic health record, but I just mentioned computer-assisted diagnostics. That can actually be included. It is software, with any other compilation of functions. So you can call up radiological images and apply that analytical software to it.

So are we saying that computer-assisted diagnostics, because if FDA were to assure it is safe and effective when it sits as standalone program on a computer, if I combine it with other functions suddenly, you don't assure it is safe and effective.

That doesn't make sense. It is the same risk to patients. Why would we do that? Why would we create arbitrary categories like that? That would be a concern.

Mr. WAXMAN. There can be real complexities of what look like simple definitions.

Dr. SHUREN. Right.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman. I now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I appreciate the ranking member of the full committee and the subcommittee in this line of questions. But I also was listening to the chairman talk about a question about when was the first time you provided some technical assistance on legislation—on this piece of legislation, and my understanding was, following up with staff, was late last night was the first time they had any of these discussions. So I would ask my colleagues to hear, Congresswoman Blackburn, are you willing to work with the FDA to try to clean up some of this language that might be of concern?

Mrs. BLACKBURN. Absolutely, and that is why we had contacted them in July and continued to seek to work with them. It is about making certain we do not stifle innovation providing certainty and clarity.

Mr. SHIMKUS. And Dr. Shuren, would you then work with Congresswoman Blackburn and the bipartisan group cosponsoring this legislation, to see if they can reconcile some of these language differences?

Dr. SHUREN. We certainly would be more than happy to work with you, and I will say in terms of request for feedback on legislation, we did provide some feedback within the agency in July. I don't know whatever came back to you all. And I was on the first version of the bill. The new version of the bill. To my understanding, we were first asked for any kind of feedback late last week. And we did take a look at the bill, and we spoke, I think, with one of your staffers.

Mr. SHIMKUS. Just reclaiming my time, I think the point being made is, I think you have the author of the legislation, and we have, I think, your commitment to work together because there are issues raised by the ranking member, I think are credible, but it is a good piece of bipartisan legislation that they worked on. Mr. Waxman, would you like to comment?

Mr. WAXMAN. I thank you for yielding. I am always open to discussing the matters, but it seems to me there is a threshold question of whether we need legislation at all, and I am not convinced of that. But I would certainly be happy to talk to——

Mr. SHIMKUS. Reclaiming my time, I am going to raise one of those issues of why we might need legislation, and it goes back to Mr. Pitts' other question, based upon this issue of Christy Foreman's testimony, where she basically said that that guidance could change.

Now, Mr. Pitts' question to you was, can that guidance change at any time? And in good bureaucratic form, Dr. Shuren, you said, well, not immediately. Well, that wasn't the question of whether it could change immediately. The question was, could that guidance change?

Dr. SHUREN. Yes, it could change.

Mr. SHIMKUS. OK, that is the answer we are trying to get out. But I do know that in her testimony, she said could change its mind tomorrow, and I think that is probably where you talked about no immediate response. But the point being that guidance could change, and the importance of codifying is that then the law would have to change, which brings us to the point of why the legislation might be important, and because in the tech industry, they need—just like any other business—they need some certainty. And because of the two additional points that I have would be with this, is what would you tell companies who fear the FDA regulation with an imprecise tool like an medical device regulatory tool who fear that regulatory confusion and delay are sure to follow the September 2013 final guidance. You are saying there is none. Is that correct?

Dr. SHUREN. Well, I am just saying that we did provide a lot of clarity in the guidance, and we have a mechanism to continue to build on that. So companies who say you know what, I am doing this specifically, I would like to get feedback from the agency, we will look at and quite frankly, no, we shouldn't be dealing with that. We will put that on the Web site so everyone learns.

Mr. SHIMKUS. Let me reclaim my time. I have got a minute left. There are really small companies, and this is how these folks start as we all know, who are being—maybe the excitement is being diminished based upon the FDA regulatory regime and so larger companies, not that there is any here in this crowd, might be trying to purchase smaller apps, or proposals, or inventions because of the bureaucratic challenge of getting through the FDA and this process. I only put that on the table because we represent constituents, and this is what has been raised to us.

So I put that just as one of the reasons why certainty might be helpful, more certainty might be helpful than less. And with that, Mr. Chairman, I yield back my time.

Mr. PITTS. The chair thanks the gentleman. I now recognize the gentleman, Mr. Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Thank you very much, Mr. Chairman, and I won't take the full 5 minutes. I think my colleagues have covered some of the territory that I intended to cover. But thank you, Mr. Chairman, for holding this hearing. I am one of the six individuals who have been referenced here as sponsors for this bill. I think it is important. I have listened very carefully to this conversation, and certainly, I understand the concerns that Mr. Waxman and Mr. Pallone have raised, and I think it is—they are legitimate concerns and I think we need to work through this as we go forward.

But the reason I have signed on to this bill is just because of the explosion of software in this space. These applications have just exploded over the last 12 to 18 months, and we have got to get some type of regulatory framework to make sure that it does not have unintended consequences. I don't want to discourage innovation. Innovation is the future. And I want to keep us on the cutting edge, and we can do that. And so I pledge to you, to all of you who are stakeholders in this, that I will work with you to try to come up with a framework that we can all agree on.

Speaking of stakeholders, I have in my possession, six letters that I received. Mr. Chairman, I am going to ask unanimous consent to submit these six letters of support for the SOFTWARE Act that we have received from health care industry.

Mr. PITTS. Without objection. So ordered.

[The information appears at the conclusion of the hearing.]

Mr. BUTTERFIELD. And if I may state for the record, these letters are from Aetna Health, Healthcare Leadership Council, Health IT Now Coalition, Verizon, and IBM, and Applications Developers Alliance. Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman. I now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. LANCE. I thank you, Mr. Chairman, and I will not take my full 5 minutes. It is always a pleasure to be with you, Doctor. Do you know, does the FDA currently have reciprocity agreements with the agencies with which it is working? I know that the Congress has decided that there will be a regulatory framework where no one agency would prevail in all matters. Do you currently have reciprocity agreements?

Dr. SHUREN. We do have MOUs in place.

Mr. LANCE. MOUs, you will have to tell me what that is.

Dr. SHUREN. Oh, I am sorry, Memorandums of Understanding.

Mr. LANCE. Memorandums of Understanding.

Dr. SHUREN. And Office of the National Coordinator is part of Health and Human Services so that is actually part of, if you will, one happy family.

Mr. LANCE. One happy family. Rather like Congress, one happy family. As an example, if an app developer finds a bug in its software that causes a potential patient safety risk, as I understand it, it will typically issue a patch as quickly as possible to fix the functionality. Since the threshold for submitting a change is whether the change could significantly affect the safety or effectiveness of the device, wouldn't the FDA require that it review the patch before the developer could release it? And if that is correct, wouldn't that mean that a change that actually improves the safety of the app might be held back for months until approval is received?

Dr. SHUREN. Yes, we actually don't generally ask to see those security patches before they may—in fact, most of the changes in software, we don't look at beforehand. But it is a great point about what you do with software, and you should know that there is currently an international effort underway under the International Medical Device Regulators Forum that you encourage us to be a part of under FDASIA, to develop an international harmonized framework for software as a medical device, because all of these other countries, they have been regulating software medical devices for years. And now it is about do we have a common appropriate framework in place? We have been asked by industry to do that and we are actually working with industry on that.

In fact, the U.S. is chairing that effort, and it deals with what do you do when there are changes in software, and how best to accommodate the business models of companies that make software, but also assure proper patient safety, and that is underway right now.

Mr. LANCE. Thank you, Dr. Shuren, and Mr. Chairman. I yield back the balance of my time.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman. I am proud of the efforts of the group of original co-sponsors of the SOFTWARE Act, and this bill has been supported by the Healthcare Leadership Council, the Bipartisan Policy Center, Information, Technology and Innovation Foundation and several others. It is an important first step toward Congress fulfilling our obligation to provide the FDA the tools necessary to do our jobs.

Dr. Shuren, thank you for being here today. And I am pleased with the guidance issued by the FDA, and I appreciate all your hard work and leadership. Under this guidance, are most electronic records regulated?

Dr. SHUREN. Under this guidance, we are not regulating electronic health records.

Mr. GREEN. OK. Under this guidance, would mobile apps aimed at diagnosing and prescribing medical care be regulated?

Dr. SHUREN. Certain diagnostic apps, but the ones that are, you know, just certain treatment recommendations, no, but certain diagnostics ones, yes.

Mr. GREEN. Can you distinguish between those for those of us who are not physicians?

Dr. SHUREN. Yes. So what we have said is the kind of functions we have been regulating all along, we have already approved. We have approved devices for that or cleared. Just because they moved to a mobile platform, we would treat them the same. So I mentioned the ECG machine. We have a mobile app for an ECG that doctors can use a smaller smartphone to use to diagnosis patients in their office and help determine if someone is having a heart attack. We want to make sure it is safe and effective. Whether it is a box this big or it is a box that big, it is still the same function.

Mr. GREEN. OK. The FDA is using enforcement discretion to establish a risk-based framework for regulating these products. Is that correct?

Dr. SHUREN. We are using—we are actually just using enforcement discretion to clarify the kinds of mobile apps that we are not enforcing any requirements. That is it. It is not creating any new framework at all.

Mr. GREEN. So future administrations could make different decisions?

Dr. SHUREN. So in order to do that, the good guidance practice, the way it works is that there is a very extensive public process to make any changes in it. It is not easily done, it is not done overnight, but the value of it is that things change over time. People sometimes come back and say you know what, we tried this policy for a while, we need new clarity, because things have changed. Guidance lets us do that. When we have statute, we can't do that. We don't have that flexibility. Guidance does.

And one of the things about changes here, what would change? Well, we also said there are certain things we used to regulate it, we are not regulating anymore. We anticipate over time and more input from the community and more experience, there will be more things we say we used to regulate, we don't regulate. We can do that through guidance. That is what enforcement discretion allows us to do. Statute provides limitations.

Mr. GREEN. OK. It appears, though, that virtually all software used in the health setting could be regulated under some administrations and could not under others. I know that discretion helps, but somewhere along the way there needs to be certainty, regulatory certainty, but mostly important could endanger the patient safety in the future.

Dr. Shuren, I commend you and your agency for recognizing your need for clarity and certainty. If clarity and certainty are the goals, why shouldn't we work on legislation?

Dr. SHUREN. So as I said before, it is certainly your all prerogative to do so. And if you all want to do that, we are very happy to work with you. I just simply put out, put in place what some of the challenges are with statute. There is a desire for predictability and flexibility. Statute, it can give you predictability, it doesn't give you that flexibility to be able to adapt as technologies adapt, as the marketplace evolves and, as stakeholders say, you know what? We need to see some changes. We are able to better accommodate our stakeholders through a guidance mechanism in many cases than we have with statute. And I am not saying that

legislation may not be necessary in the future. All we are saying is it is premature at this point, particularly in not even figuring out what does a new framework look like?

And in that respect, maybe the line's drawn going different places. Maybe at that point there is a need to put something in legislation, or maybe we want something out there and get experience with it first before we have decided whether or not we got it right, because we got it wrong, it is much harder to change statute than it is to change guidance if necessary, but it is not easy to change guidance either.

Mr. GREEN. Believe me, we understand that, but the concern I have is that we need to have both, we need to have some flexibility with the FDA, but also certainty to industry and everyone else that they know what the FDA's doing. And if FDA should want certainty that comes from updated regular authority through legislation, and if not the right time, how will we know when the right time is to start? After a public health crisis? And, again, our committee just dealt with compounding, because—and the first hearing did not show very good on the local pharmacy agency in Massachusetts or the FDA, and so we have put together a bill that, again, nothing's perfect we do, but that actually gave the FDA that authority, discretion, but certainty in the authority of it.

Mr. Chairman, thank you. I know I am out of time.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Chairman. I appreciate it very much. Thanks for holding this hearing as well. Thank you, Doctor, for your testimony.

The first question, Dr. Shuren, under the rules you issued, FDA said it would have enforcement discretion on many commonly-used applications, for example, apps that serve as video conferencing portals specifically intended for medical use and to enhance communications between patients and caregivers; also, apps specifically intended for medical uses that utilize a mobile device, built-in camera or a connected camera for purposes of documenting or transmitting pictures to supplement or augment what would otherwise be a verbal description.

This sounds like FDA reserves a right to regulate Skype, Web cams, iPhones and tablet PC's. There are many off-the-shelf software solutions that can be used or adopted into telemedicine, as you know. How do you draw the delineation of a program specifically intended for medical use?

Dr. SHUREN. Yes. So actually the tablets, the tablets themselves and the video cameras and all that, those aren't even medical devices. I don't even view them as medical devices. The issue has come up when someone develops software and they use the smartphone, let's say, the person developing the software that suddenly gives it a medical function. So I mentioned the ECG. Another one is ultrasound. People use sound waves to look at abnormalities in the body, so we have cleared an app that is an ultrasound. It takes kind of a mobile platform and it turns it into a medical device. The maker of that platform is not a manufacturer of medical devices; no responsibility on their part.

The software, though, is the issue. And the challenge there is, and as this bill is currently drafted, the problem for us is we wouldn't be able to assure that that software is safe and effective. And it is used by, sorry Dr. Burgess isn't here, an obstetrician to use on women who are pregnant to look for fetal abnormalities. And in this case, we wouldn't be able to assure that this is going to be accurate technology when a doctor uses it to make sure the fetus is healthy or not healthy. Those are the things that we are talking about, but a basic tablet by itself is not even a medical device.

Mr. BILIRAKIS. Even if it is used for medical purposes?

Dr. SHUREN. No. That itself isn't. The software maker, then, is actually taking that tablet and as part of it is now using it as a medical device. The software maker, then, whoever is putting that together, they are the ones who have now put out a medical device through their software. The person who made the tablet, Apple, is not a device manufacturer, and that is what we have said.

Mr. BILIRAKIS. OK. And in the mobile medical app guidance, mobile platforms are defined to include smartphones, again, tablet computers or other portable computers. Is a laptop considered a portable computer?

Dr. SHUREN. It is a portable computer. And we don't regulate laptops.

Mr. BILIRAKIS. What about——

Dr. SHUREN. And I have got to tell you, I don't want someone regulating my iPad. I like my iPad.

Mr. BILIRAKIS. What about a desktop?

Dr. SHUREN. A desktop is a computer, right.

Mr. BILIRAKIS. Not considered a portable computer?

Dr. SHUREN. No.

Mr. BILIRAKIS. OK.

Dr. SHUREN. And what you are highlighting is what has changed over time is that you have a lot of the same functions, but you didn't have the capability to make tiny computers. That is the way the world changed. I had things years ago that are on a desktop, and then the laptop came along, we had the PCs, and now they can be on small smartphones. They are computers. And the value is that they can play a variety of different software. Manufacturers don't have to make the hardware anymore, because they now have ubiquitous hardware that a software maker can simply take advantage of.

That is the way the world has changed. And all we are saying is the functions, when they stay the same, treat them the same, because the impact and the risk to patients are the same. Simply because it got smaller and I can pick it up and walk out of the room with it doesn't change the risk for patients. Why, for that reason alone, would we simply treat it differently?

Mr. BILIRAKIS. OK. I have heard some, including staff at the FDA, suggest that the FDA move to regulate mobile medical apps, will give industry and patients more certainty. Can we really say that enforcement discretion gives health IT developers and investors any certainty or clarity if the FDA can indicate that it may, that it may have the discretion to change its policy? Is that the case? In other words, can we—instead of—because the FDA has the

discretion, how does that give the industry or developers any certainty?

Dr. SHUREN. Because there are safeguards in place to actually change that discretion. As I mentioned, there are a lot of statutory requirements for us to go through under good guidance practices with putting out proposals, public comment, and congressional oversight before we can make any kind of changes. So it is not a simple thing for us to do, particularly when there is disagreement on it, but a number of cases, we have our constituents come and ask us to change guidance because the times change and they want updates, and the guidance lets us do that. That is the value of it. And we hear time and time again from our industry how much they want guidance, because it gives them both predictability and flexibility. That is why we have been increasing our guidance production, because we have been asked to do that by our industry. They find it of tremendous value.

Mr. BILIRAKIS. OK. Thank you. I yield back the balance of my time. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentlemen and now recognizes the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. CASTOR. Well, thank you, Mr. Chairman. And thank you, Dr. Shuren, very much. I think this is a very exciting area, all of the advances in health information technology. I have seen it help boost small businesses back home and create business opportunities across my community in the Tampa Bay area. I think that the mobile apps hold great promise in improving people's health, also empowering consumers and individuals and providing more efficient tools for medical professionals.

Now, the 2012 FDA Safety and Innovation Act, FDASIA, directed FDA to work with the Office of the National Coordinator of Health IT and the FCC to propose a strategy and recommendations on an appropriate risk-based regulatory framework pertaining to health information technology, including mobile medical applications that promote innovation, protects patient safety and avoids regulatory duplication. FDASIA requires the working group of the three agencies to report to Congress by January of 2014.

Dr. Shuren, can you tell us what steps the three agencies have taken so far in developing that report and the extent to which outside stakeholders have had an opportunity to provide input into the development of that report?

Dr. SHUREN. Well, certainly. We constituted a multi-stakeholder working group, so representatives from all different parts of the ecosystem under the Office of National Coordinators Health IT Policy Committee, and they spent time and they got a lot of public input along the way, they put out draft recommendations, they got public input on that, and provided it to us. We have gotten a lot of input from the stakeholder community, both from that working group and from other meetings and venues in which we have participated, and that is helping to inform the report that we will make available to Congress and we will make available to the public.

And as I had mentioned, we will get public comment on that before even proceeding to put out proposals for anything that would

go into a regulatory framework. So trying to have a very thoughtful process moving forward.

Ms. CASTOR. And are you satisfied that the participation has been very diverse? Are small businesses adequately represented, are academics represented, the larger corporations? Has everyone had an opportunity? Is there enough balance in what you have heard so far?

Dr. SHUREN. We think there has been. I am sure you can always hear from people who said, wow, I wish I am in the room and I am part of a committee. Then you have a committee of thousands. So it is always challenging, but in spite of that, there are publicly available dockets where people provide information, there are meetings where any member of the public could come and to talk, and of course, people can always request to talk to us directly. We talk to lots of people who want to have those conversations, and we do so.

Ms. CASTOR. So are you still on track for January 2014?

Dr. SHUREN. I am anticipating it is going to be a little bit later, in all fairness. We have the recommendations from the working group came in September, and we had the government shutdown, so some people were not around working on things, it adds a little bit more time, that is why I say more likely February, certainly the first quarter, but the final decision after it goes up to review will be made by others, but our goal is to get it as close to that line as we can.

Ms. CASTOR. And do you think it is important for the Congress to have the benefit of those recommendations before we consider whether or not to legislate in this area?

Dr. SHUREN. We do, because we have got a wealth of information to provide back. And like I said, Congress can decide at any moment if you all want to pass legislation, it is your discretion to do so. We would like to make sure that any decisions made are with full information, and then I think there will be value coming from the report. In fact, may even feel that at that point if additional comment, we think there will be need for a lot more input from stakeholders before even sort of figuring out exactly what a framework looks like and what the pieces are, and even then, delving a little bit deeper into the specific aspects of it, because this is complicated.

It was hard enough even drawing the lines that we did in guidance that is 40 pages long that is just simply about things that are in or out for FDA, nothing about stuff that is about how you treat them, and we knew that was a 2-year process, but how important stakeholders felt it was to have the opportunity to provide input and really think it through.

And all we are asking is sometimes moving quickly to judgment leads to unintended consequences that can be very hard to undo once they are done, and that is all we are really trying to put on the table. We share your desire to promote innovation, and we share your desire to protect patients. We want to see this field flourish. We are jazzed up about a lot of the technology. We want it to happen. We want it to happen right. And that is why we are moving about it in the way that we are doing it and trying to do it in a very collaborative fashion.

Ms. CASTOR. Good. I look forward to reading your report early next year. Thank you.

Mr. PITTS. The chair thanks the gentlelady and now recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you. Hey, thank you for coming back today. I appreciate you being here. As I have talked to different people who provide apps, and I know you said we do not intend to regulate iPads, it is the apps that go on the iPads, and depends on what that app is that goes in the iPad. And I am not an attorney, but I had one law school class and I know the exams were always not black or white, it is always somewhere in the middle, that is the questions they always asked and where does the gray intersect each other. And so just kind of—and they would give you scenarios. I was just looking through a scenario that people have brought to my attention. And I will be slow so you can follow, but it says, among the mobile apps for the FDA intends to exercise enforcement discretion are mobile apps that perform simple calculations routinely used in clinical practice. It says, according to the FDA, these apps are intended to provide a convenient way for clinicians to perform various simple medical calculations taught in medical schools or routinely used in clinical practice.

And so the question is, while dosing calculators are not listed among the examples, if a specialist routinely prescribes a certain drug patients, would an app that calculates the proper dose be considered not regulated, or would that app be considered one that performs sophisticated analysis and therefore is regulated?

Dr. SHUREN. So we think a lot of those actually would not be regulated. And this is why we ask and why we created this mechanism for people who then have questions, say, well, here is what we are looking to do. Is this the kind of thing that you approve clearcut or something you are not exercising new enforcement discretion to? Because in the past, we regulated that as a medical device. We had a classification for it and now we are saying we are no longer doing it. And those are the cases where, particularly as we expand and enforce the discretion, clarity around it, we want people to ask us and we will put those examples on our Web site. But there are other kinds of——

Mr. GUTHRIE. So they have pre-clearance if they are going—because it makes a decision on your investment according to where you think the time is going to take to be approved.

Dr. SHUREN. Oh, yes. And we have actually provided that for developers for years. They have always had the opportunity to come and ask. Here we are trying to have a much more streamlined mechanism to get feedback to developers very quickly and let them know, and give them the kind of certainty they look for. But when you draw a line, think about even statute, in a few sentences, that is still very broad. The question is, what does it mean? And then even with a bill, we are going to have to move forward and interpret that and provide clarity around that, and then there will be additional questions about, well, what did that mean? And we will go through the same kind of exercise. It will always be these issues of, does this mean I am in or I am out, and we will always be in a position of having to provide that kind of clarity.

Mr. GUTHRIE. Because that would be very helpful that you are going down that path. And actually I was going to kind of continue that application, but I think that the answer will be the same. You will have to get pre-clearance when you move forward down that path, so——

Dr. SHUREN. Yes. And you don't need pre-clearance, because if you went out there on the market and we strongly said, yes, you are the kind of stuff we are not touching, that is fine, you don't have do come to us.

Mr. GUTHRIE. Right.

Dr. SHUREN. We offer it as a service. If you want to and ask us, we can do that. We provide even an email address to send it in. And I will tell you, for these that are coming in, where there is any kind of question about it, it actually—it comes up to a group, I sit on that group. We are actually meeting this week. And we have questions that come in, and we are answering them.

Mr. GUTHRIE. Yes. I guess I—I understand on pre-clearance. So I just have an app on my phone that calculates how far—if I walk to the Washington Monument, it calculates my heart beat and whatever, that type of thing, or if I have an app on my phone that—I don't have diabetes, but if I have a diabetic pump and it regulates that, that obviously clearly would have to be regulated.

And I guess the question when people start getting, the example, one I had is—I was going to go through, maybe I should, like, look, you wouldn't regulate it if it was just downloading the Physician's Desk Reference, and I just had that on my phone instead of in a book, because you don't regulate the book—but I will go through an example, I have about a minute, then. I have an example of Coumadin, a blood thinner that could cause major or fatal bleeding. The full prescribing information in the Physician's Desk Reference gives the list of patient-specific factors that impact the proper dosing of Coumadin. And since this information is being used in the mitigation, treatment or prescription by a facilitating professional assessment of the specific patient, should it be in a different category of apps? And MMA guidance is inconsistent on how the FDA intends to oversee dosing information. So that can kind of blur the lines——

Dr. SHUREN. Yes. And what——

Mr. GUTHRIE [continuing]. In dosing calculators.

Dr. SHUREN. We are moving toward a place where a lot of the dosing information is taking a step back and letting a lot of that happen. We are already doing that. I am anticipating we wouldn't do more. But then we talked about dosing for radiation and how complex a calculation that is, and that is one where it is not so simple. Someone can't figure it out very—themselves with paper and pencil, if you will, very quickly. That can take weeks. You got a physicist, radiation oncologist. That is the kind of dosing. So if you just blanket any kind of dosing, you would sweep that in. Those are the kinds of challenges.

But I would say even with statute, you will always have the issues on boundary lines and seeking for clarity, because I will tell you, with the law we have today, on any of a variety of different areas, we are always providing a different clarity to people. It is just a question of do you draw a line that locks you in and still

have to provide the clarity, or do you give flexibility to a community that itself is evolving, and we don't know what the future will look like. Shall we tell people, your future is locked in today or do we want to let the community have the ability to let the marketplace evolve. And we would like to see the marketplace evolve.

Mr. GUTHRIE. Thank you. I yield back.

Mr. PITTS. The chair thanks the gentleman. Now recognize the gentlelady from the Virgin Islands, Dr. Christensen, for 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you. Thank you, Mr. Chairman. Welcome, Dr. Shuren. So we have heard a lot so far about the substance of the guidance FDA recently issued, all that went in to developing it and how you are working with the developers, and that has really been helpful, but I think it would be useful to have some more context. And sort of to follow up on my colleague's last set of questions, I would like to ask you about the background and history of FDA's oversight on software generally.

Your testimony mentions the fact that FDA has been regulating medical device software for decades and medical device software on mobile platforms for more than 10 years. This would, I am sure, surprise many people, because software is not typically thought of as being a medical device. So could you explain to us how software can be a medical device again under the Food and Drug Cosmetic Act? Obviously you don't regulate all software. It would also be helpful if you could give us—you gave us some examples of where you have exerted regulatory oversight, but some examples of software that you might have begun with decades ago and things you are looking at today.

Dr. SHUREN. Yes. Certainly. So, the device definition was written broad, with the idea that it is in place to allow for changes in technology over time. So how it becomes a device is because it is intended for use in diagnosis of disease or conditions or treatment-cure mitigation of disease, and not doing so primarily by chemical action. If it is chemical action, it is a drug, not chemical action. It can be a device. And it is the same approach, by the way, other countries also have that broad definition which allows them to handle new technologies as they come up.

We have technologies now that are moving to mobile platforms. So another one is fetal monitoring. We have now an app for that. And this is typically used on women who have a fragile pregnancy to monitor for uterine contractions, fetal heart rate and determine is the fetus is in distress. It is used in hospitals for that purpose. Our concern is under the bill as currently drafted, we wouldn't be able to assure that is safe and effective.

What is on the horizon? Diagnostics, lots of diagnostics. They are all going to be on mobile platforms. The XPRIZE just put out a challenge to develop a Tricorder. Now, I am a Trekkie. Remember Dr. McCoy had what was probably the first mobile medical app in history. He had a Tricorder, and he would wave this little handheld thing over the body and he would make a diagnosis.

Well, the XPRIZE Foundation put out a challenge for that, to actually have technology to diagnose diabetes and stroke and heart disease. And guess what? Today that technology is going to become

a reality, because there are ways of measuring things in the blood without taking your blood.

Mrs. CHRISTENSEN. Right.

Dr. SHUREN. And they approached us, because they said, these are medical devices. We have got to make sure it is safe and effective. Will you work with us to provide guidance to these developers, and we are doing this. This is a partnership. I would love to see a Tricorder. Can you imagine "Star Trek" in reality? It is like a kid's dream come true. That is the future. But we want to be there to help the future, and we would be concerned on anything in legislation that doesn't provide those assurances for patients.

Mrs. CHRISTENSEN. And so would I. So obviously FDA has had a lot of experience in this space, and that is really very reassuring. And medical devices, they fall into different tiers, Tier I, Tier II and Tier III. Of course, Class I devices are the least risky and III are the riskiest.

Can you briefly elaborate on these three levels of device oversight and the responsibilities the device manufacturer has under each of these levels?

Dr. SHUREN. Certainly. So Class I is our lowest. That is low risk. We don't review those going on the market. And about 50 percent of devices on the market today are probably Class I. And they have to have labeling, they have to report certain serious problems to us or, we have some surveillance, and they have to do something called quality systems. Some people call it good manufacturing practices, but in engineering, we call it quality systems, and it is having the practices and procedures in place to assure you make a quality product. And this is actually a linchpin in making good products.

And we believe the future, by the way, in software really focuses much more on quality systems and a post-market approach to many things, and that is what is under discussion in this international effort.

Class II are moderate risk. And in addition to what I talked about for requirements, we do see them beforehand. And that case, we do a comparison of a substantially equivalent to other technologies on the market. That is a 510K.

And the very high risk, Class III, we then ask for studies to show are they, in fact, safe and effective? So we have a very risk-based approach.

As I mentioned, though, all of this is looking at being modified for purposes of software. Exactly. And that is the same we are doing with Europe, Canada, Australia, Japan, China, Russia, and we have the Asian Harmonization Working Party, which if they agree too, will bring in other countries in Asia, the Middle East, and Africa into one harmonized framework.

Mrs. CHRISTENSEN. Thank you.

Mr. PITTS. The chair thanks the gentlelady, now recognizes the gentleman from Virginia, Mr. Griffith, for 5 minutes of questions.

Mr. GRIFFITH. Thank you so much, Mr. Chairman. And I apologize that I was not here earlier. I am working in another committee as—or subcommittee as well.

Doctor, I understand your hesitation about setting things in stone, especially considering how quickly this industry is evolving.

However, the medical industry as a whole is evolving quickly, as you know. Your comments beg the question whether Congress should ever legislate in this space. Our goal here is to carefully craft legislation that sets your authority in stone, but does so in a flexible manner that provides you the authority for effective regulation of the industry.

My colleague, Mr. Green, in his opening statement mentioned the issues that arose during the meningitis outbreak. Throughout the investigation and legislative process that followed that outbreak, we learned that the FDA felt it lacked regulatory clarity and authority. We all want to make sure that the FDA is in a position to regulate effectively and confidently. I appreciate Mr. Green bringing up this comparison, because it is an incredible lesson we learned about the importance of FDA authority and making sure that the FDA understands what its authority is.

Throughout the hearing, we have heard from everyone the promise of health IT technology. We know this industry is growing and holds enormous potential. You would agree, wouldn't you, that we have an opportunity to set a sound regulatory foundation for such pivotal technology?

Dr. SHUREN. For Congress to do that, it is always Congress's discretion to pass legislation, absolutely.

Mr. GRIFFITH. And one of the concerns that I have had, and I am so glad that we have this bill as a vehicle to work on these areas, is that when we had a previous witness in testifying, I brought out my cell phone. I have now got a newer version that does more things by about five-fold than my old one did. And I brought out my cell phone and I said, hey, here is the problem. A group of scientists in Africa working with people in Canada and the United States and Switzerland, I believe, came up with an $8 hack onto a cell phone that allowed them to take high resolution pictures of fecal material, and folks in the United States were then telling them what parasite was affecting the village in Africa.

I said, is that going to be considered a—if we were to try to use something like that in the United States, would that be a medical device? And the lady said, yes, I believe it would be, because it is diagnostic. An $8 hack on a cell phone is a way that we can bring a lot of innovation into diagnostics, et cetera, and particularly when—and I am representing a largely rural district in Virginia, and I had one of my hospitals recently close down, and we are hoping that we can rectify that, but now I have got folks who have to travel 45 minutes to get cardiac care.

It sure would be nice if we had some high tech fixes, and they are on the verge of being there, where my folks could hook up directly with the doctor, if that technology were readily available. And I am just afraid the FDA may slow it down by having too much. So don't you think something like this bill is necessary?

Dr. SHUREN. So in all honesty, we don't believe such a bill is necessary, or certainly at this time. And part of the issue, the difference with compounding, in the compounding case, FDA came back and said there is not clarity, to my understanding, clarity in the law, we needed clarity.

Here we think we have the authority. We are using enforcement discretion, if you will, to adapt to changing technology.

I will say that example with stool, no, we wouldn't be regulating that. We just had that with melanoma. If you take a picture of skin and you are sending it to a doctor, no, we are not touching that, but software that is analyzing that melanoma, we just ran into it with an app developer who sold it to consumers and said, look, use this on your skin lesion, you have a concern, we will tell you if it is high risk or moderate risk or low risk, and if it is high risk, we will recommend you go see a doctor, and if it is moderate or low risk, you just monitor it; not go and see your doctor, monitor it.

And guess what? When researchers at the University of North Carolina looked at it, it was accurate in finding melanoma one out of 10 times. Nine out of ten times it missed it. It was telling patients, don't go see your doctor, monitor it. That is a diagnostic and that is the kind of stuff we should be concerned about.

Mr. GRIFFITH. Well, and I understand that, but I also risk—there is also the risk that if we don't get things out there onto the marketplace, that people may miss something, because those people who got that test, even with its low accuracy rate, may not have been planning to go see a doctor anyway, and some of them, one out of 10 at least, did go see the doctor. Now, I would prefer it if obviously they didn't have a false read, and that is an issue that has to be taken up.

Dr. SHUREN. Yes. And those folks obviously downloaded the app because they were interested in looking at some suspicious skin lesion. Again, we are not looking to hold up technology.

I will say of the feedback we have gotten on the guidance is, for the most part, you know, you have got the line in a good place. I mean, and we were trying to get to that point of providing the clarity that people are seeking. It is not easy. Whichever way we do it, statute, guidance or whatever, it is not easy to draw perfectly clear lines, and that is why it took 2 years to even get to where we were.

Mr. GRIFFITH. But 2 years is a long time. I do appreciate it.

And I am hearing the signal that my time is up, and therefore, Mr. Chairman, I yield back.

Mr. PITTS. The chair thanks the gentleman. I now recognize the vice chair of the subcommittee, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman. And again, Dr. Shuren, thank you for being with us today. Back in my opening statement, I talked a little bit about clinical decision support. Back in my day, that meant the Merck manual in the pocket of your white coat as you went down to the emergency room, but now it can be so much more real-time and it can be up-to-date. And it really, in my opinion, is one of those things that could really transform the way doctors practice. Do you agree with that observation?

Dr. SHUREN. I do agree with that. And we actually think for clinical decision port, and this is why we have been asked to provide clarity in that area, but we were asked to give more time and do it as part of this other process on a regulatory framework, we do think a lot of those things are not the stuff that FDA would be touching. Even things—IBM, I am glad they are here, things they are doing with WatsonPaths we have seen and they are going through data import, those are not the stuff that we are touching.

We think that is terrific. But the way the people start—then the question is, how do you define?

So even the bill today which, again, as drafted, draws a line that actually cuts out things like the computer-assisted diagnostics that even the same groups that have said, oh, maybe we would like statute, those are exactly the examples of what they say FDA should regulate. And that is what we kind of mean about we are drawing the lines on this. We want to make sure the kinds of things that we should be looking at, we at least have the ability to do that to assure for doctors and patients are safe and effective, and the other things we are not going to touch. That is our idea.

Mr. BURGESS. Well, do you see where there is a concern that as long as there is some ambiguity as to whether or not you might regulate it in the future, it leaves them with the ambiguity of not knowing how to proceed on the development side?

Dr. SHUREN. I would say typically for folks who have dealt with us, and understand how we use our policies——

Mr. BURGESS. Be careful. I have dealt with you.

Dr. SHUREN. I know you have. I know. See, you even caught me off guard right there. Thank you so much.

That being able to make those changes is not something that can be done on a dime. And that is why for folks who have dealt with us understand that, yes, we actually do have a level of certainty. In fact, what they tend to ask for is more guidance and more clarity as opposed to, please don't use guidance to clarify for us.

Mr. BURGESS. But, I mean, it is a little bit of a different world than the typical drug device world in which you have historically regulated. Is that a fair statement?

Dr. SHUREN. Yes, but one of the things that has happened here in terms of where we are looking, we didn't move out into someone else's space and say, you know what, we are coming out to reach new stuff. What has happened is developers, who weren't making things in the health care space and FDA, typical kind of FDA regulated functions started to say, well, now we are going to go do that. And what they did is they kind of moved into a world we have been dealing with, and for them it became, ooh, we don't know the FDA. We hear of things. We are concerned.

So we didn't reach out to actually expand our universe of anything in our guidance. We have been contracting it. But we have new players. And this has happened before in other times. New people come in, they have uncertainty about us, and that is why we are going through this extensive effort to engage with folks and provide the clarity so that we think over time, the people who aren't used to dealing with us will realize, oh, now we get it, we are good, but that will take time.

Mr. BURGESS. That is exactly the point. The developers who have uncertainty about dealing with you, how can we provide them the stable footing they need to proceed with their—and we want them to proceed with their developments. I mean, this is the golden age of medicine that stretches in front of us, so we want them to proceed. How do we give them the certainty that they can be surefooted in traveling down that road?

Dr. SHUREN. By doing what the health IT working group, the multi-stakeholder groups asked us to do: to continue to provide

that clarity through guidance in other areas, like clinical decision support, in accessories, on certain claims, and that is what you are likely to see in the report we send up to you all, is saying these are the things that we should do. We should follow up on those recommendations and put out that clarity through guidance as we have been asked to do.

Mr. BURGESS. Well, I apologize I wasn't here, but apparently Representative Lance asked you about the updates to apps, that the apps that the FDA does regulate, the up—it seems like my iPad or iPhone is always telling me I have got to update my apps. So everyone's familiar with the facts that apps have to be updated. Are you regulating the updates to the apps as well?

Dr. SHUREN. Yes. So most of the kinds of updates, we see the software, we don't even look at coming in the door. And I mentioned, too, there is an international effort underway for international harmonization on how software as medical devices approach and that includes modifications. And this is a collaborative effort between government and industry.

So all of this is included. This is an evolving area. It is another reason why, too, some of these things we are not locking in at all because it is evolving. Those discussions are happening. And we want to get to a place where we and Europe and Canada and Australia, China, Russia, Japan and elsewhere are acting in that same way, have harmonized approaches, because we think that ultimately is in the best interests of everybody. That means a technology treated—a software in the U.S. Gets treated the same in Europe. We would love to see that happen and that is what we are working on, and that includes modifications.

Mr. BURGESS. All right. I wish I shared your certainty. But thank you, Mr. Chairman. You have been kind. I will yield back.

Dr. SHUREN. Well, consider it enthusiasm rather than certainty at the moment.

Mr. PITTS. OK. The chair thanks the gentleman. That concludes the questions from the members. The members may have follow-up questions. We will get them to you in writing. Ask you to please respond promptly.

To confirm what I heard from you today, Dr. Shuren, you have committed to work with Representative Blackburn and her colleagues, and I would ask that your assistance, collaboration be responsive and timely.

And before I introduce our second panel, thank you, Dr. Shuren, for all of your responses, your testimony.

I ask unanimous consent to include in today's hearing record a letter from AdvaMed, which includes their comments on H.R. 3303 and issues related to regulation and health information technology. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. With that, you are dismissed, and I will call the second panel to the table. We have five witnesses, and I will introduce them as they come and the staff sets up.

First, Mr. Mike Marchlik, vice president, Quality Assurance and Regulatory Affairs, McKesson Technology Solutions; Mr. Jim Bialick, Executive Director of Newborn Coalition; thirdly, the Honorable Zachary Lemnios, vice president Research Strategy, IBM Re-

search; fourth, Mr. Robert Jarrin, senior director of Government Affairs, Qualcomm Incorporated; and finally, Dr. J. Leonard Lichtenfeld, deputy chief medical officer of the American Cancer Society.

Thank you all for coming. Your written testimony will be entered into the record. You will each be given 5 minutes to summarize your testimony. And Mr. Marchlik, we will start with you. You are recognized for 5 minutes to summarize.

STATEMENTS OF MIKE MARCHLIK, VICE PRESIDENT, QUALITY ASSURANCE AND REGULATORY AFFAIRS, MCKESSON TECHNOLOGY SOLUTIONS; JIM BIALICK, EXECUTIVE DIRECTOR, NEWBORN COALITION; HON. ZACHARY J. LEMNIOS, VICE PRESIDENT, RESEARCH STRATEGY, IBM RESEARCH; ROBERT JARRIN, SENIOR DIRECTOR, GOVERNMENT AFFAIRS, QUALCOMM INCORPORATED; AND J. LEONARD LICHTENFELD, DEPUTY CHIEF MEDICAL OFFICER, AMERICAN CANCER SOCIETY, INC.

STATEMENT OF MIKE MARCHLIK

Mr. MARCHLIK. Good morning, Mr. Chairman and distinguished members of the subcommittee. My name is Michael Marchlik. I am vice president of Quality Assurance and Regulatory Affairs for McKesson Technology Solutions.

Today I am speaking on behalf of more than 15,000 technology employees. Together, we are transforming health care from a paper-based system to one empowered by interoperable electronic solutions. Our focus is to improve patient safety, reduce the cost and variability of care, and advance health care efficiency.

McKesson strongly supports H.R. 3303, the SOFTWARE Act. This bipartisan legislation recognizes that a 40-year-old statute should be updated to reflect innovation and the importance of health IT.

Prior to joining McKesson, I spent 30 years as a quality and regulatory professional in the medical device and nuclear industries. This experience gave me a unique perspective on effective risk-based regulatory frameworks as well as how traditional medical device manufacturing differs from health IT development.

At McKesson, I have faced the challenge of applying a 40-year-old law to technology that did not even exist 4 years ago. FDA rules are designed for physical devices, which undergo slower incremental changes and longer development cycles, where a focus on manufacturing processes makes sense. That environment is markedly different from software, where improvements, updates and patches are made available in a matter of days.

The SOFTWARE Act creates a regulatory framework that acknowledges the difference between medical devices and health IT, recognizes the different categories of health IT, and focuses FDA oversight on the technology that poses a greater potential risk to patient safety. This legislation is the culmination of many efforts to address how health IT should be regulated in the 21st century. Under the auspices of the Bipartisan Policy Center, BPC, I represented McKesson in working with more than 100 hospital, physi-

cian and patient organizations to develop recommendations for a new risk-based regulatory framework for health IT.

In a March hearing before this subcommittee, my colleague, Dr. Jackie Midas, testified that health IT is foundational to improving the quality, safety and affordability of health care. She emphasized that a new risk-based regulatory framework distinct from medical device regulation and specific to health IT is necessary. We believe that the SOFTWARE Act is a critical step forward to achieving that vision.

The SOFTWARE Act establishes three distinct categories of health IT: medical software, clinical software and health software. Medical software acts directly on a patient without the ability of a clinician to intervene. Clinical software, by contrast, does not act directly on the patient, but rather informs the clinician's treatment of the patient. Health software is used by clinicians not to treat patients, but rather to schedule appointments, process claims and analyze data.

Under the SOFTWARE Act, medical software would continue to be regulated by the FDA, clinical software would be subject to a new oversight framework developed by Congress and the administration, and health software would not be subject to additional patient safety regulation.

These three software categories are consistent with both the principles described in the BPC report as well as historic FDA software guidance. FDA has little expertise in clinical software development and implementation and does not regulate the practice of medicine, nursing or pharmacy, where software is ultimately customized and used. That is why we believe that clinical software requires a new regulatory framework that reflects first the dynamic nature and rapid innovation of health IT; second, the shared responsibility among health IT vendors and providers who developed, configure and use the systems.

The SOFTWARE Act will update current law to provide clarity on how best to ensure patient safety while promoting innovation and broad adoption of health IT. It replaces non-binding FDA guidance and enforcement discretion with the certainty needed by the highly innovative health IT industry.

In conclusion, we urge Congress first to pass the SOFTWARE Act, which is critically important to setting the guideposts for a new policy; second, to provide oversight to the administration when implementing this policy; and third, to continue to work with stakeholders to establish the effective risk-based framework to appropriately regulate cutting-edge health IT.

On behalf of McKesson, I appreciate the opportunity to testify in support this legislation and commend the sponsors for your leadership. I am happy to answer your questions.

[The prepared statement of Mr. Marchlik follows:]

OVERVIEW OF STATEMENT OF

MICHAEL MARCHLIK
VICE PRESIDENT - QUALITY ASSURANCE AND REGULATORY AFFAIRS
MCKESSON TECHNOLOGY SOLUTIONS

McKesson supports HR 3303, *the Sensible Oversight for Technology Which Advances Regulatory Efficiency Act*, also known as the SOFTWARE Act. This bipartisan legislation is an important and necessary step toward establishing a new regulatory framework for health IT that recognizes the different categories of health IT solutions and focuses Food and Drug Administration (FDA) oversight on the technology that poses a potential risk to patient safety. It is a logical step forward to help realize a safer, more modern healthcare system.

Applying a four decade old approach to mobile and cloud based technologies that did not exist even four years ago is ill advised. Under the current law, the FDA regulates medical software under the broader category of "medical devices," a term that was defined by amendments enacted in 1976 to the Food, Drug and Cosmetic (FD&C) Act. There is an important distinction between the regulation of traditional medical devices and the regulation of rapidly evolving technology.

The existing FDA regulatory framework is not well suited for regulating clinical software. Medical devices and the medical software that operates these devices act directly on a patient, and potential harm stems from how the device or software is designed and manufactured. In contrast, the risks to patients from clinical software are associated with how the software is customized, implemented and used by providers (hospitals and physicians). Clinical software requires a new risk-based regulatory framework that reflects the shared responsibility among health IT developers, providers who are implementing and customizing the systems, and, ultimately, the clinical and administrative personnel who use these systems in the delivery of healthcare.

The FDA's expertise is in overseeing quality control and manufacturing processes. The Agency has little expertise in the area of clinical software implementation and use. Additionally, the FDA does not regulate hospitals or the practice of medicine, nursing or pharmacy, and, therefore, has little, if any, involvement in healthcare operations, including use of clinical software in care delivery by hospitals and clinics.

The SOFTWARE Act establishes three distinct categories of health IT: medical software, clinical software and health software. This legislation calls for the FDA to continue to regulate the highest risk category of "medical software" and charges Congress and the Administration with collaborating in the development of a **new** risk-based regulatory framework for "clinical" and "health" software. These classifications recognize that the risk associated with health IT, and hence the intensity of regulatory oversight, should be based upon the severity of potential harm to the patient as well as the opportunity for a clinician to intervene between the technology and the patient.

We urge Congress to:

1) pass the SOFTWARE Act, a critically important step in setting the guideposts for a new policy;
2) provide oversight to the Administration in implementing this policy; and
3) continue to work with stakeholders and industry to establish an effective risk-based framework to ensure that modern-day health IT is appropriately regulated.

November 19, 2013

STATEMENT OF

MICHAEL MARCHLIK
VICE PRESIDENT - QUALITY ASSURANCE AND REGULATORY AFFAIRS
MCKESSON TECHNOLOGY SOLUTIONS

BEFORE THE
ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH
U.S. HOUSE OF REPRESENTATIVES

EXAMINING FEDERAL REGULATION OF MOBILE MEDICAL APPS AND OTHER HEALTH SOFTWARE

November 19, 2013

Good morning Chairman Pitts, Ranking Member Pallone and distinguished members of the Subcommittee. My name is Michael Marchlik, and I currently serve as Vice President of Quality Assurance and Regulatory Affairs for McKesson Technology Solutions. I am here today on behalf of more than 15,000 McKesson employees who work every day on the development and deployment of health information technology (IT) solutions that improve the quality and safety of patient care.

I appreciate the opportunity to testify in support of HR 3303, *the Sensible Oversight for Technology Which Advances Regulatory Efficiency Act*, also known as the SOFTWARE Act. This bipartisan legislation is an important and necessary step toward establishing a new regulatory framework for health IT.

Prior to joining McKesson, I spent 30 years as a quality and regulatory professional in the medical device, nuclear and process industries at organizations such as Becton Dickinson, Duke Energy and Arthur D. Little. This experience has provided me with a unique perspective on effective risk-based regulatory frameworks and an appreciation as to how health IT software development and delivery differs from traditional medical device manufacturing.

For 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the nation's largest distributor of pharmaceuticals, we pride ourselves on the efficiencies that we bring to the healthcare system by delivering safe medicines every day to pharmacies, hospitals, physician offices, skilled nursing facilities and government locations, including every Department of Veterans' Affairs facility, across the country.

As the largest health IT company in the world, McKesson is actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency.

McKesson strongly supports the SOFTWARE Act which is a logical step forward to help realize a safer, more modern healthcare system. This bipartisan legislation provides critical clarity regarding the regulation of a broad array of health IT or medical software.

As you are aware, under the current law, the Food and Drug Administration (FDA) regulates medical software under the broader category of "medical devices," a term that was defined by amendments enacted in 1976 to the Food, Drug and Cosmetic Act. The definition of medical device in the Act is so broad that it can be, and has been, interpreted to include *all* health IT. In my role at McKesson, I recognize the important distinction between the regulation of traditional medical devices and the regulation of rapidly evolving technology. Applying a four decade old approach to mobile and cloud- based technologies that did not exist even four years ago is ill advised.

My previous twelve years of experience with a large medical device manufacturer has helped me appreciate that FDA rules are optimized for physical devices which undergo slower incremental changes subject to well defined, expensive development processes. In these circumstances, the burden of Good Manufacturing Practice (GMP) regulations makes sense because variations of one-thousandth of an inch could result in patient harm. That environment is markedly different from agile software development where patient risk is not measured by precise manufacturing standards but relies equally on the development and deployment of the technology.

The SOFTWARE Act creates a regulatory framework that recognizes the different categories of health IT solutions and focuses FDA oversight on the technology that poses potential risk to patient safety. The legislation will promote patient safety while continuing to foster innovative medical advancements so critical to the quality and efficiency of healthcare.

Government and Industry Engagement

This legislation is the culmination of numerous efforts over the past two years to address how health IT should be regulated in the 21st century.

1) The FDA Safety and Improvement Act of 2012 (FDASIA) includes a requirement that the FDA, the Federal Communications Commission (FCC) and the Office of the National Coordinator for Health IT (ONC) develop and submit to Congress by the end of this year recommendations for a new risk-based regulatory framework specific to health IT.

2) Under the auspices of the Bipartisan Policy Center (BPC), McKesson helped lead the development of consensus recommendations for a new risk-based regulatory framework for health IT in conjunction with more than 100 hospital, physician and patient organizations, IT and health IT companies. These recommendations are outlined in the BPC report: *An Oversight Framework for Assuring Patient Safety in Health Information Technology*, which was released in February 2013.

3) In a March 2013 hearing before this subcommittee, my colleague, Dr. Jackie Mitus, testified that health IT is foundational to improving the quality, safety and affordability of healthcare. She also emphasized that a **new** risk-based regulatory framework, **distinct** from medical device regulation and **specific** to health IT, is necessary.

4) Over 140 healthcare organizations signed a letter sent to the Administration in June 2013 urging it to collaborate with Congress in the development of a risk-based statutory

framework for regulation of health IT while supporting innovation and patient safety. Signatories ran the gamut from health IT startups to large public companies, from physicians' organizations to think tanks and major hospitals.

The introduction of the SOFTWARE Act is an important bipartisan milestone recognizing that a 40 year old statute must be updated to support rapid innovation essential to improving the quality and delivery of healthcare and reducing cost.

SOFTWARE Act

The SOFTWARE Act establishes three distinct categories of health IT: medical software, clinical software and health software. This legislation calls for the FDA to continue to regulate the highest risk category of "medical software," and charges Congress and the Administration with collaborating in the development of a **new** risk-based regulatory framework for "clinical" and "health" software.

These classifications recognize that the risk associated with health IT, and hence the intensity of regulatory oversight, should be based upon the severity of potential harm to the patient as well as the opportunity for a clinician to intervene between the technology and the patient. We agree that it is appropriate to regulate technology that directly acts on a patient ("medical software") differently from software that merely aggregates information and renders a recommendation to a clinician ("clinical software"). Administrative software ("health software") that supports the administrative and operational aspects of healthcare but is not

used in direct delivery of clinical care should not be subject to any regulatory oversight. These categories of medical, clinical and health software are consistent with the logic and principles described in the BPC Report and provide a sound basis for distinguishing amongst the broad array of health IT solutions.

The existing FDA regulatory framework is not well-suited for regulating clinical software. Medical devices and the medical software that operates these devices act directly on a patient, and potential harm stems from how the device or software is designed and manufactured. In contrast, the potential risks to patients from clinical software are associated with how the software is customized, implemented and used by providers (hospitals and physicians). Clinical software requires a new risk-based regulatory framework that reflects the shared responsibility among health IT developers, providers who are implementing and customizing the systems, and, ultimately, the clinical and administrative personnel who use these systems in the delivery of healthcare.

The FDA's expertise is in overseeing quality control and manufacturing processes. The Agency has little expertise in the area of clinical software implementation and use. Additionally, the FDA does not regulate hospitals or the practice of medicine, nursing or pharmacy, and, therefore, has little, if any, involvement in healthcare operations, including use of clinical software in care delivery by hospitals and clinics.

Finally, the distinctions between the categories of health IT defined in the SOFTWARE Act are consistent with historic FDA guidance on software regulation. Specifically, the FDA issued a draft guidance document in 1989 that exempted from regulation administrative software, including patient administration and accounting software. Diagnostic and clinical decision support software were also exempted, if the program required "competent human intervention before any impact on health occurs." While this guidance was later withdrawn in 2005, FDA acknowledged that direct interaction with the patient and the opportunity for clinical intervention are significant factors in determining risk.

Clear Congressional Policy Needed

Mr. Chairman, throughout the course of the debate on the SOFTWARE Act, you may hear testimony that current regulation of health IT by the FDA is working successfully. It is true that the guidance set forth by the FDA on mobile medical applications, the Agency's approach to enforcement discretion, and its participation in the FDASIA working group have been thoughtful and productive.

But, as my colleague, Dr. Mitus, said last March: "We are using a 40 year old law to regulate rapidly changing and dynamic technology." Non-binding guidance and enforcement discretion do not provide the clarity that a highly innovative industry like health IT requires.

The SOFTWARE Act updates the current Food, Drug & Cosmetic Act to provide clarity to the Administration and industry on how best to ensure patient safety while promoting innovation and broad adoption of health IT.

We urge Congress to:

1) pass the SOFTWARE Act, a critically important step in setting the guideposts for a new policy;
2) provide oversight to the Administration in implementing this policy; and
3) continue to work with stakeholders and industry to establish an effective risk-based framework to ensure that modern-day health IT is appropriately regulated.

Mr. Chairman, health IT is imperative to the successful transformation of healthcare. It improves quality and patient safety, enables payment and delivery reform, promotes efficiency, lowers cost and drives patient satisfaction. It is an essential building block of everything we are trying to accomplish in healthcare reform. That is why it is so important that we regulate it thoughtfully.

The SOFTWARE Act establishes different categories of health IT, meters oversight appropriately according to relative risk, and sets the stage for a new regulatory framework that reflects the shared responsibility for patient safety. We appreciate the opportunity to testify in support of this important legislation and commend the sponsors for their leadership on this significant issue.

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Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman, Mr. Bialick, 5 minutes for your summary.

STATEMENT OF JIM BIALICK

Mr. BIALICK. Chairman Pitts, Ranking Member Pallone and members of the subcommittee, thank you for the opportunity to testify today on this very important issue. My name is Jim Bialick. I am the executive director and co-founder of the Newborn Coalition.

The Newborn Coalition is an all volunteer organization that works domestically and internationally to promote the development and safe and effective use of health technologies for newborns.

This hearing is very timely and it is appropriate that Congress takes a deeper look into the many complexities of our regulatory system, identifies the limits of what can be improved administratively, and determines where legislative action is necessary. To argue that Congress does not have a role in reforming the way technology is regulated is to say that regulators already have all of the tools they need to be effective in fulfilling their statutory mandates.

While I recognize that some have come to know the existing regulatory process better than others, the agencies themselves have identified that there are a number of barriers to effectively regulating health information technology that are broken at the level of the written law. This means that even if the agencies wanted to fix the problem, legally they could not, and Congress has to intervene. To me, there is little certainty in doing nothing, especially when doing nothing means not addressing problems that the regulators themselves say they have, and especially when doing nothing is at the expense of those regulators fulfilling their statutory mandate of protecting patient safety, including the stakeholders I represent, which are our newest and most vulnerable citizens.

Technology, such as mobile apps, are playing a central role in transforming our health care system, but their impact will be muted unless there is a concerted effort to clarify how products will be regulated. Efforts across regulators must be coordinated and shift the way we think about medical devices away from discrete products to a focus on the highest risk components of integrated networks and medical devices and consumer products. The line between medical and consumer devices has been blurred by the evolution of this dynamic marketplace, and only Congress can bring the needed clarity to the process.

In my written testimony, I lay out seven recommendations from the Newborn Coalition perspective on action Congress and the administration can now put in place a framework that will scale the needs of the marketplace while keeping patient safety paramount. Among those recommendations are the following: First we recommend that Congress should create a bright line that defines FDA's authority over high-risk medical devices. Enforcement by definition, is discretionary, and will need to be constantly updated to address emerging technologies.

Our disagreement with those who believe regulation by guidance, such as the FDA guidance on mobile medical applications creates

certainty, is we believe that that certainty will evaporate as technologies evolve and the process will have to begin anew.

Six members of this committee have sought to address this issue head on with a SOFTWARE Act. We support these efforts for being among the first to recognize that technology regulation should shift away from the assumption that novel use of medical device data constitutes a new device, acknowledge that technology will continue to evolve, and focus on evaluating the components of a system or network that pose the greatest threats to patient safety.

I would argue that the authors recognize placing today's definitions around future medical devices means our sights are lowered rather than focused on the horizon and the innovative technologies we cannot yet begin to imagine.

Second, we recommend Congress require HHS to contract with independent private certification bodies that would certify non-FDA technologies as safe and effective. Newborns are not little adults, but facing limited treatment options, doctors often use the smallest available version of an adult device on babies to fill gaps where newborn-specific products do not exist. We believe, however, that these medical devices can be made more valuable by health information software that supports these tools. Newborn-specific medical devices should continue to be regulated by the FDA and be subject to significant pre-and post-market evaluation.

We do, however, support an alternative certification process for companion health information software. We are engaged in this issue because we have seen health information technology save the lives of newborns, and because in the absence of devices designed for specifically for newborns, data created by adult-focused medical devices will be of only limited utility unless they are paired with health information software that can curate the data to make it more relevant to newborn care.

Health information software is not meant to replace clinicians. Software will enhance the value of the device data, and if it does not adversely impact the function or usability of the clear device it interoperates with, then the software should not be considered a new medical device in and of itself. I would stress that data is not a medical device and does not fit within statutory mandate of FDA. A public-private certification process is a more appropriate means for reviewing these technologies as they come to market.

In summation, there is no magic bullet, but with a level of interest from Congress, the administration and a diversity of stakeholders, it would be a shame to miss this opportunity to reform the system in a way that will foster innovation and improve patient safety for this generation and the next.

I thank you very much for the opportunity to testify and I stand ready to help the committee in any way possible, and I am happy to answer any questions.

[The prepared statement of Mr. Bialick follows:]

Testimony of Jim Bialick
Co-Founder and Executive Director, Newborn Coalition

To the Energy and Commerce Committee
Subcommittee on Health

Examining Federal Regulation of Mobile Medical Apps
and Other Health Software

November 19, 2013

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee,

Thank you for the opportunity to testify today on the very important issue of regulation of mobile medical apps and other health software. My name is Jim Bialick and I am the Executive Director and co-founder of the Newborn Coalition. The Newborn Coalition is an all-volunteer organization that works domestically and internationally to promote the development and use of safe and effective technologies for newborns.

Current Landscape

This hearing is very timely and this issue directly impacts healthy babies and those with special needs. There have been a number of events over the last few months, with others forthcoming that will help determine how health technologies are regulated:

- In early September, the Food and Drug Administration Safety and Innovation Act (FDASIA) Working Group released its final recommendations to the Office of the National Coordinator for Health Information Technology's (ONC) Policy committee on the strengths and weaknesses of the current regulatory process for health technologies. The Workgroup indicated there are issues "broken in law" that only Congress can fix;

- In late September, the Food and Drug Administration (FDA) finalized its Guidance of Industry and Agency Staff outlining how it will use its enforcement discretion in the regulation of Mobile Medical Applications (MMA);

- In October, six members of this Committee: Vice Chairman Blackburn alongside Representatives Green, Gingrey, DeGette, Walden, and Butterfield introduced H.R. 3303 – the Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act of 2013, a bipartisan bill addressing the changing nature of medical technology and how it should be regulated; and,

- By January 2014, the HHS must release a report containing a strategy and recommendations on a risk-based regulatory framework pertaining to health IT, including mobile applications, which promotes innovation, protects patient safety, and avoids regulatory duplication.

These actions represent efforts by both Congress and the Administration to address how the changing health technology market should be regulated. With so much activity on this issue, it is fitting and appropriate for Congress to take a deeper look into the many complexities of our regulatory system, solicit stakeholder input, identify the limits of what can be changed administratively, and determine where legislation is necessary.

Impact on Newborns

Newborns are an inherently high-risk population. They are difficult to diagnose and to treat, their bodies are very sensitive, and it is often difficult to quantitate how much a baby has developed at the time of birth.

For these reasons medical devices with indications for newborn populations are appropriately subject to more regulatory scrutiny and post-market evaluation, which has led to a relatively small market for newborn-specific devices.

In addition, the high costs associated with pre-market regulation of newborn-specific products has caused a number of medical device manufacturers to shy away from designing products specifically for newborns and to instead bring similar products to market with adult indications. Newborns are not little adults, but, facing limited treatment options, doctors often use the smallest available version of an adult device on babies. In this sense, newborns are underserved by our healthcare system. While we argue that more should be done to incentivize the development of newborn-specific devices, we also believe that we should promote the innovative analysis and use of all device data to make it more relevant to newborns.

Our ultimate goal is to improve health outcomes and lower costs for newborns and their families and we fundamentally believe the expanded availability and use of medical device data is central to this pursuit. Mobile apps and the smartphones and tablets are easily accessible, intuitive, and commonly used by parents. These technologies will continue to play a central role in healthcare but their impact will be stunted unless there is a concerted effort to allow these technologies a way to access and creatively use clinical data to better inform the decision making by both providers and parents in the ongoing care of a newborn.

Congress should clarify existing statute to distinguish information systems from traditional medical devices so that more can be done with data from existing products. We believe that newborn-specific medical devices should continue to be regulated by the FDA and be subject to significant pre and post-market evaluation. We do, however, support an alternative certification process for companion information systems that are designed to interact with regulated medical devices or networks of devices in novel ways.

We believe there are three major areas of work that must be undertaken to foster the transparency and efficiency needed to align the statutory mission of regulators with the needs of the market:

1. Update the definition of a Medical Device to reflect the evolving nature of medical technologies by differentiating between those that manage health information and those used to diagnose and treat patients.

2. Create an alternative certification pathway to market for health information software, which may interact with a device or network of devices, to ensure they reliably function as designed.

3. Create a collaborative mechanism for robust post-market surveillance that incentivizes safety and addresses adverse events quickly with a mix of punitive and non-punitive enforcement options.

Congress alone has the power to set many of these changes in motion but we believe that it will be through an iterative and deliberate process defined by collaboration between Congress,

regulators, and other relevant stakeholders that will bring about a scalable, transparent, and competitive health system for new technologies where safety is paramount.

Aligning the Statutory Roles of Regulators

The road to market for industry is crowded with regulators and the potential for duplication, which is costly and time consuming. While the volume of emerging technologies has strained the current regulatory process, it remains functional because the majority of medical technologies coming to market are discreet and fit reasonably into regulatory silos. The convergence of technologies and multi-function devices is challenging the current regulatory paradigm because many products combine functionality that has historically been evaluated by more than one regulator. The FDASIA Work Group highlighted an example of where regulation is very clearly duplicative in its recommendations to the ONC Policy Committee:

> FCC and FDA do not coordinate their review processes on converged medical devices that are brought independently before both agencies (FCC's equipment authorization program and FDA's premarket review). Coordination between agencies should be transparent and help ensure consistency thereby eliminating duplicative, time consuming, and costly hurdles. – *FDASIA Work Group Presentation to the Policy Committee September 2013*

This duplication will be most commonly seen in enforcing FDA's final guidance on the regulation of Mobile Medical Applications (MMA). The available computing power and portability of smartphones and tablets has made them a popular platform for patients and providers alike. Applications may leverage the cellular connection on a smartphone or tablet to access wireless spectrum, something currently regulated by FCC.

The MMA guidance is very clear that the onus of passing through the 510k or PMA process falls on the MMA developer, not the smartphone manufacturer. This means that a smartphone manufacturer will continue in the FCC Equipment Authorization (EA) program and not be drawn into the FDA process for merely providing a platform for a MMA to function.

This does not mean the FDA will *not* evaluate the smartphone at all. If a MMA is designed to leverage a smartphone's cellular connection then the FDA will evaluate that functionality in its pre-market review in the context of ensuring the MMA can function as designed. FCC, however, has already certified the smartphone's ability to access wireless spectrum through the EA program making FDA's evaluation of the exact same capabilities in its pre-market review process duplicative.

Despite the fact that the MMA guidance was released weeks after the FDASIA Work Group made its final recommendations, it does not seek to clarify how FCC EA certification will be used or regarded in the FDA process. And it remains unclear, outside of the non-binding HHS report due out at the end of the year, what specific options are available for improving interagency collaboration. It may be the case that options for fundamental changes to coordination across regulators are limited or non-existent. In its recommendations, the FDASIA Work Group identified a number of issues across FDA, FCC, and ONC that are "broken at the

written law level," or that cannot be remedied without a legislative change. Statutory limitations and the costly nature of regulatory duplication raises two complementary issues that may require legislative clarification:

1. **There is no transparent mechanism for regulatory reciprocity across agencies.**

   It is unclear how; if at all possible, increased interagency coordination could allow regulators like FCC and FDA to use the certification or evaluation completed by another agency in the fulfillment of their own statutory duties. This change may not be administratively possible within the confines of existing statute and should be clarified legislatively.

2. **No single entity has a complete view of all health technology regulation.**

   FDA may regulate a single device that accesses wireless spectrum (FCC EA program); that makes marketing claims about its intended use, user, or functionality (FTC Health Claims guidelines); and that curates information to coordinate care in hospitals (ONC-ACB). In the absence of a single entity with a longitudinal view of the regulation of health technologies, this duplication will only worsen as technologies become more convergent.

   FDA has been a leader in mitigating *intra-agency* duplication through the Office of Combination Products[1], which governs drugs with a technology component such as a pill with an ingestible RFID chip. FDA created the Office as a gatekeeper to mediate intra-agency jurisdictional disputes. Allowing an entity within HHS to act as a gatekeeper that would nationally coordinate *interagency* regulatory efforts, would infuse efficiency into the process, allow all regulators to better target their limited resources on effectively fulfilling their statutory duties, and allow the regulatory process to remain transparent and nimble as technologies evolve. Implementing such an approach, however, could not be achieved through administrative changes and would require Congressional intervention.

Updating the Definition of a Medical Device

FDA currently regulates medical devices as well as companion technologies that in some way use or interpret a device's actions or the data they create; this includes implantable devices, diagnostic tools and laboratory tests, among others. Over time, FDA has expanded its working definition of a medical device beyond its original statutory definition into other health-related technologies through sub-regulatory guidance and enforcement discretion.

As the computing power consumer devices have evolved, technologies such as smartphones are able do things previously thought to be impossible. The usefulness of these mobile devices has blossomed in recent years is due to their ability to act as a platform for a myriad of applications that extend their functionality far beyond the ability to make and receive calls. Mobile apps have transformed our cellular telephones into our cameras, our maps, and in some cases our doctors. What were originally multiple different technologies have all converged onto a single, very powerful platform.

The convergent nature of the technology market is making it increasingly difficult to put new products into traditional regulatory boxes and in the not so distant future it will become impossible. This is particularly important now that the MMA final guidance is effectuated. Many in industry were pleased with the final product because they think it brings certainty in how existing products will be regulated.

The Newborn Coalition's mission is to promote the development and use of safe and effective technologies in the newborn period while leveraging that technology to create better health outcomes throughout that child's life. Considering the pace of the marketplace and the needs of newborns, we would be profoundly disappointed if the technologies of today remotely resemble the technologies available to our core constituency by the time they have children of their own. Our disagreement with those who believe that the final MMA guidance creates certainty, is that we believe the certainty will evaporate as technologies evolve..

Enforcement discretion by definition is discretionary and will need to be constantly updated to address emerging technologies. We question the ability of the current regulatory system, with its limited resources and staff expertise, to address these new demands. We believe there is still an opportunity to put policies in place that will allow the flexibility that accommodates a changing marketplace before the needs of the market dwarf the capabilities of regulators and our current system.

Creating a New Definition of Technologies

We believe this process begins with updating the definition of a medical device to mean only those technologies that pose the highest risk to patients. Congress should work with FDA to focus agency resources on technologies that pose the highest risk by creating a bright line between medical devices and health information software that may interact with a medical device.

We offer the following definition as a guideline in clarifying when a technology is medical in nature and therefore poses a higher risk to patient safety:

> *A technology becomes medical in nature when it is designed or marketed to change or evaluate the end user's current state physiology without informed context or with limited or no time for informed human intervention.*

The unique nature of human physiology is a significant variable that may make a device function out of its expected range and harm the end user. This specific concept is what makes these technologies medical devices and why they require strict oversight and pre-market evaluation: they are engineered around an unknown, which is the end user's physical individuality.

We believe Congress should create a bright line between technologies that function as high risk medical devices and that should be regulated by the FDA, and those that are lower risk that should fall outside the FDA process.

This Committee has already begun to address the need for a distinction by introducing the SOFTWARE Act of 2013. As mentioned previously, the concern from the patient community with the current process is that it only addresses technologies that exist today and does not give sufficient clarity as to what will be regulated as a medical device in the future. The approach taken in the SOFTWARE Act differs from the guidance-led process used by the FDA because it very clearly distinguishes between what the FDA will regulate and what is outside of their jurisdiction.

Establishing this line means Congress should also address how non-medical devices that fall outside the FDA process should be determined safe and effective. We believe this requires an alternative certification pathway.

Alternative Certification Pathway for Health Data Systems

When the function of a technology is not dependent on analyzing or changing the user's current state physiology it is inherently lower risk because it is more predictable. These technologies can be certified in lieu of the FDA approval process because premarket evaluation of the product will be an exercise in engineering, not biological science. A certification process will ensure the safety of health information software by ensuring it adheres to known standards for information exchange with one or more regulated medical technologies without changing or adversely affecting the original functionality or usability of the devices that are cleared by the FDA.

To be successful, a certification-based regulatory pathway must require that products adhere to consensus based technical standards to execute their core functionalities. Further, developers must be transparent in the technical standards used in the design of a product and provide guarantees that their product does not engage in restrictive business practices that may limit a technology's ability to interoperate with a secondary system or adversely impact the integrity data during an exchange.

The American National Standards Institute (ANSI) accredited standards development organizations (SDOs) and the International Organization for Standardization (ISO) go through in-depth processes to convene multi-stakeholder working groups to drive consensus on standards that meet a particular need in the market, implement them throughout industry, and subsequently audit programs to ensure they have been properly implemented. Standardization strengthens the integrity of data used across multiple technologies, creates clarity for developers that aid in design and operation, and incentivizes industry to collaborate on the development of new standards thereby creating a holistically more interoperable marketplace.

There are several models already used in federal programs that could be a basis for certification of health information software. Most notably are the ONC-ACBs used in the Meaningful Use program that certify electronic health records or EHR modules and accommodate the large number of vendors participating in the program. These are private sector technology and standards experts contracted with the ONC to ensure technologies operate according to program standards. Since the beginning of the Meaningful Use certification process in 2010, nearly 5,000 products have been certified for use in the program[ii]; many of which are being used in Medicaid

hospitals and are greatly improving care coordination and the portability of health data for newborns.

ONC was able to ramp up its certification process quickly because it used a decentralized model, identifying certifiers and test beds that had the regulatory expertise to effectively test that EHRs and EHR modules could comply with previously identified certification criteria. It is important to clarify that requiring adherence to known standards is very different than mandating how those standards must be used. The FDASIA working group, in its final report, noted that EHR products brought to market after the beginning of the Meaningful Use Program were being built to meet the quality measures laid out in the program and not necessarily the diverse needs of providers and their patient populations. This so-called "compliance innovation" dilutes the effectiveness of the free market and should be avoided whenever possible.

The challenge in implementing a certification program to address a diversity of technologies with applications in healthcare is that there will be significant variation in functionality, product engineering, and the ability for systems to interoperate. The goal of basing a new regulatory model around adherence to standards is to ensure that a product will function as designed when connected or networked with other technologies. Public-private certification relationships can address this concern.

Currently FDA deals head on with the issue of design and technical standards between products, having to develop unique test beds for new products as they move through the 510k or PMA process. Allowing independent, contracted software experts to certify these technologies will greatly expand the speed and venues available to developers to bring technologies to market. It would also address the diversity of expertise required in regulating a diverse marketplace.

While the certification program will require strict governmental oversight, the certifiers should be encouraged to compete on quality and attract customers (vendors) by establishing a race to the top for patient safety endorsements that are sought after by patients and providers alike.

Costs are a significant barrier for many moving through the FDA process. A public-private certification program can lower these costs by supplanting annually set user fees with certifiers competing against one another on price. We see this in the ONC certification market today. Private certification entities may also have more capacity in certifying certain technologies, and therefore may be able to offer evaluation of a product more expeditiously, an attractive quality for developers seeking to speed products to market.

Competition over cost and quality, paired with strict governmental oversight, will create a virtuous cycle of efficiency gains and quality improvement that will address many of the issues FDA is facing due to limited resources and regulatory expertise. A public-private certification process is an appropriate means of fostering this competition and, when paired with the certainty of updated regulatory definitions and robust post market surveillance, the system as a whole will continue to improve over time.

Post Market Surveillance

There are many health technologies that have the potential to pose significant risk to patients that are not currently regulated by the FDA. Electronic Health Records (EHRs) have evolved well beyond simple file storage and have become increasingly integrated into the delivery of clinical care. In the next stages of Meaningful Use, providers will be required to attest to having implemented a minimum of five Clinical Decision Support (CDS) interventions tied to quality measures and the delivery of care. This requirement fundamentally transforms an EHR, which was previously an administrative tool, into a clinical tool.

As noted, EHRs are not regulated by the FDA but are certified by the Office of the National Coordinator for Health IT (ONC). ONC has the power to enforce agreements with Accredited Certification Bodies (ACBs) and their Test Labs but it does not have the statutory authority to audit functionality to intervene when required functionality of a certified EHR, such as information exchange, is prevented due to restrictive contracts or business practices.

Some adverse events related to technology are not an issue of design or standards: some technology vendors—as well as some providers—pursue business practices to create what are called "walled gardens," strategies that block information sharing between different systems in order to capture market share. It is important that we identify and quickly remedy this problem as it occurs as the practice fundamentally diminishes the value of health IT, forces taxpayers to subsidized suboptimal business practices that consolidate markets and lead to price and cost increases, , and directly threatens patient safety.

Creating an office within HHS or expanding ONC's authority to audit or intervene in cases of adverse events related to health information technology, including information blocking, would improve the overall safety of our health system and greatly inform the certification or regulatory processes across all Agencies.

Similar to the gatekeeper described previously with a view across all regulators, a comparable entity is needed to facilitate post market surveillance. Models for such a body exist: FAA coordinates the Aviation Safety Information Analysis and Sharing (ASIAS) System, which is a collaborative effort between Airlines and government to openly exchange safety information in order to continuously improve aviation safety. ASIAS has the ability to access public and private aviation data, air traffic control reports, weather, and maintenance reports. The body allows the FAA and NTSB to quickly identify and remedy accidents and near missies so that they do not happen again.

Imagine such an entity for health information technology: an open collaboration between regulators, industry, patient safety organizations, ACBs, providers, and the patient community with access to timely data reported across agencies for the purposes of continuous quality and safety process improvement. This would have a significant and immediate impact on health technologies particularly as they converge with consumer products and become more integrated into our daily lives. Creating a mechanism for these entities to openly collaborate in a protected way would allow regulators engaged in post-market review to identify problems and develop solutions before an adverse event or near miss harms another patient.

Suggestions

Updating the existing regulatory process to safely bring products to market at the speed of innovation will require some statutory changes only possible through legislative action. Congress has the opportunity to take immediate steps to remedy the most pressing obstacles to effective regulation and to lay a foundation for a systemic reform in the near term. The Newborn Coalition, in collaboration with providers, industry, and patient advocates, has compiled seven specific ways Congress can act immediately to improve patient safety:

1. Focus FDA's resources on medical technologies that change or evaluate the end user's current state physiology without informed context or with limited or no time for informed human intervention. Congress should create a bright line that defines FDA's authority over high risk medical devices. Other technologies should fall outside of FDA's purview.

2. Require HHS to contract with independent, private certification bodies that would certify non-FDA technologies as safe and effective.

3. Require HHS to establish an office that acts as a gatekeeper to nationally coordinate interagency regulatory efforts. This gatekeeper would direct products to FDA or private certifiers as appropriate.

4. Refine the law where necessary to allow regulatory reciprocity across FDA, FCC, and ONC to eliminate costly duplication.

5. Direct FDA, FCC, FTC, and ONC to complete a collaborative report on statutory changes needed to implement a public-private certification program for health information software designed to interact with cleared medical technologies, and complete it in advance of the next Medical Device User Fee and Modernization Act.

6. Expand ONC's regulatory authority to include post-market surveillance authority, usability audits of certified and implemented technologies, and the enforcement authority to disqualify vendors or providers that engage in information blocking from federally funded programs.

7. Create a collaborative environment for adverse event reporting by expanding PSO legal safe harbors to include vendors of regulated health technologies to incentivize transparency in adverse event reporting and require all health IT products in federally funded programs have a relationship with a PSO.

Conclusion

In providing this testimony, laying out the bottlenecks and barriers we see in the current process, and in suggesting options for moving the system forward, I feel it critical to note that there is no magic bullet that will transform the system we have today into what we will need in the future.

We believe that collaboration between Congress and Regulators will be critical in identifying where the law must be updated to reflect the changing marketplace.

With the level of interest from government, industry, providers, and the patient community it would be a shame to miss the opportunity to reform the system in a way that will foster innovation and improve patient safety.

Thank you again for the opportunity to testify today. I stand ready to help the Committee in any way possible and am happy to answer any questions you may have.

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[i] Combination products are defined in 21 CFR 3.2(e)

[ii] 3,629 for Ambulatory care & 1,231 for Inpatient Care. CHPL accessed 9/12/13.

Mr. PITTS. The chairs thanks the gentleman. I now recognize the gentleman, Mr. Lemnios, 5 minutes to summarize his testimony.

STATEMENT OF HON. ZACHARY J. LEMNIOS

Mr. LEMNIOS. Good morning, Chairman Pitts, Ranking Member Pallone and distinguished members of the Health Subcommittee. Thank you for the opportunity to speak with you today. My name is Zachary Lemnios and I am the vice president of research strategy at IBM Research.

I joined IBM last December and have served in the Obama administration as the Assistant Secretary of Defense for research and engineering. Off script, I will tell you it is a delight to be back before Congress and testifying.

This morning I am going to talk about the innovations in the private sector, but I will tell you that in the defense sector, we saw remarkable progress for our wounded warriors, the technology and innovations that 5 years ago were really just in the research stage, and we should all be very proud of that.

My comments this morning are with respect to technical innovation regarding the private sector and the potential to improve health care, and how Congress and the administration can best work together to promote innovation.

IBM invests billions each year in research and development from the first continuous blood separator that led to the treatment of leukemia, to the first heart-lung machine used to keep patients alive during surgery, to the excimer laser that opened up LASIK surgery that many of us use today.

IBM research has a rich legacy of addressing health care's most pressing needs. Today we are collaborating with universities and with medical institutions to help children with—universities and with medical institutions to help children who would not otherwise have access to intensive care, to simulating the human heart to better understand how genetic variations predispose some patients to arhythmias, and to transform EMR clinical data into user-friendly formats so that patients can better understand and participate with their health care management.

The victory of IBM's Watson on the television quiz show "Jeopardy" revealed how scientists and engineers at IBM and elsewhere are pushing the boundaries of science and technology to create the machines that interact with people in very new ways. This new cognitive era promises a significant shift in the ability of people and organizations to quickly analyze, understand, and unlock the insights contained in a torrent of data that is around us.

As this subcommittee knows, health care is one of the most data-rich environments today, yet physicians are often working with limited information and shortened timelines. The results can be fragmented care, errors that raise the cost and threaten the quality of health care.

Consider this: Primary care doctors spend on an average of somewhere between 10 and 19 minutes face to face with each patient per visit. An estimated 15 percent of diagnoses are inaccurate or incomplete. Medical information is doubling every 5 years, but 81

percent of physicians spent less than 5 hours a week reading medical journals.

Advanced analytics, combined with cognitive computing, natural language processing, can help doctors efficiently assess and make use of this ocean of information to achieve individualized evidence-supported medicine. In addition, advances in technology could help address disparities of access across our Nation.

Congress can contribute to these advancements by assuring that there is a regulatory environment that encourages innovation while protecting the safety of individuals. Innovation and improved safety are not inconsistent goals. In fact, innovation can enable better tools to continuously promote learning and possibly improve care, to reducing these adverse effects.

The current regulatory framework, largely developed during the decades before the rise of today's sophisticated IT technology, focuses on traditional discrete devices, manufacturing in a single site, and physically shifted distributors and users. While some have embedded software, these are frequently physical articles placed into the commercial environment, modified relatively infrequently, and often do not interact with multiple other devices provided by parties.

With the rise of network ecosystems, and even more sophisticated software, this paradigm simply doesn't encourage tomorrow's innovation. The medical technology field is populated with multiple players who are interconnected through technology that can be rapidly and integrally improved through deep collaboration and through IT partnerships with the clinical end users.

Further, clarity is needed to enable a vibrant marketplace where the paths of bringing collaboratives to market is known. Clarity is really what we are after in this environment, and one area that calls out for clarity is clinical decision support software. This is intended to aid clinicians in making decisions rather than making those decisions directly for patients. It is one of the resources that clinicians can use, not solely rely upon, but use in their decision-making process.

Currently it is unclear whether and how CDS would be regulated, and we urge Congress and the administration to work together to clarify this, recognize that in all health care, in all software in this arena, it is not the—software is simply not the same. One size fits all is not the right equation. Using the current medical device regulatory framework to determine if and how regulation of the diversity of potential health care software would be used is something that needs to be clarified. Without this, we will quash innovation, we will delay the adoption of supporting tools that can help clinicians better provide health care.

Mr. PITTS. The gentleman's time's expired.

[The prepared statement of Mr. Lemnios follows:]

The Honorable Zachary J. Lemnios
Vice President, Research Strategy
IBM Research

House Energy and Commerce
Health Subcommittee

Examining Federal Regulation
of Mobile Medical Apps and Other Health Software Hearing
November 19, 2013

Good morning, Chairman Pitts, Vice Chair Burgess, Ranking Member Pallone, and distinguished members of the Health subcommittee. Thank you for the opportunity to speak with you today.

My name is Zachary Lemnios and I am the Vice President for Research Strategy in IBM Research. I am responsible for the formation and execution of the IBM Research strategy across IBM's twelve global laboratories and network of collaboratories. I have held a variety of senior research and business unit leadership roles in both the private sector and in government. Prior to joining IBM last December, I served as the Assistant Secretary of Defense for Research & Engineering; the Chief Technology Officer for Department of Defense.

My testimony today will focus on IBM's outlook on technological innovation and its tremendous potential to dramatically improve the quality of healthcare. I will conclude by explaining our support of the Blackburn-DeGette bill and how the Congress and the Administration can best accelerate the growth and use of these technological innovations to transform healthcare and improve the health of our Nation – its people and our economy.

First, IBM Research's experience in healthcare

Research is where we conceptualize innovation to become tomorrow's products. Few areas of health and medicine have gone untouched by the technology, research and innovation generated by IBM. Over the past several decades, IBM Research has been leading in healthcare from the first continuous blood separator that led to treatment for leukemia patients, the first heart-lung machine used to keep patients alive during surgery and the excimer laser used in LASIK eye surgery to technologies of the future that may one day allow nanoscale particles to help fight drug-resistant infections.

IBM invests billions each year on research and development, and works with teams of physicians and other clinicians to ensure it is addressing healthcare's most pressing needs. With 12 laboratories on six continents, IBM Research is working on a wide range of projects:

- IBM Research is working with Boston Children's Hospital to mature technologies that could equip doctors and nurses with the knowledge and skills they need to help under-served children who would not otherwise have access to intensive care.
- Baylor College of Medicine and IBM Research are exploring how we could accelerate the discovery of new drugs to treat and cure diseases such as Alzheimer's and ALS.
- IBM Research, Geisinger Health Systems and Sutter Health are collaborating to see if we can develop models that would help doctors detect heart failure years sooner than is now possible.
- IBM Research is working with the Lawrence Livermore National Lab to simulate the human heart (roughly 1,200 times faster than other published results) in exquisite detail to better understand how patients will react to certain drugs and how genetic variations predispose some patients to arrhythmias.
- UNC Health Care is collaborating with IBM Research to transform clinical data from electronic medical records into a user-friendly format so that patients can better understand their health information and participate in their care management plan.

Now, our outlook on technology

We are witnessing an unprecedented phenomenon today – the convergence of five simultaneously disruptive technologies: social, mobile, cloud, pervasive instrumentation and advanced analytics. Organizations and individuals are faced, constantly, with a torrent of data, everything from structured information such as transactional records to a wider variety of unstructured data, still images, video, audio, blogs, tweets, etc. This unstructured data can be tremendously useful if it can be captured and understood by humans, in a timely fashion.

At that same time, we are crossing a new frontier in the evolution of computing and entering the era of cognitive systems. The victory of IBM's Watson on the television quiz show Jeopardy! revealed how scientists and engineers at IBM and elsewhere are pushing the boundaries of science and technology to create machines that interact with people in new ways.

In this new cognitive era, we can now apply tremendous computing power to this Big Data not only to do programmable "if A, then B" logic, but also to have interpretive capabilities that will let them "learn" from the data and adapt over time as new knowledge is acquired or as demands change.

By "learn," I mean going beyond simple question and answering to understanding information, interacting with it; and interacting in a different way with the system that is analyzing that information.

It's no longer about taking a piece of the data and doing a computation. These cognitive systems are looking for the context or the correlations in those pieces of data. Some simple context examples -- these systems can learn that "noses can run" and "feet can smell"; a house can "burn up" as it "burns down" and a "wise man" might be a more welcome dinner guest than a "wise guy."

By processing information in a way that is similar to how people think, cognitive systems promise a significant shift in the ability of people and organizations to quickly analyze, understand and unlock the

insights contained in Big Data. Further, by using advances in natural language processing, this type of cognitive system can sift through vast amounts of data to provide evidence-based answers to its human users' questions.

We are imagining such systems to provide supporting evidence for each step in the answering process. This high level of transparency would help the user better understand the system and resulting evidence-based insights. It would enable the user to provide specific feedback from which the system can continually learn and it would help users extend their thought processes.

Increasingly, computers will gather huge quantities of data, reason over the data, and learn from their interactions with information and people. These new capabilities could help us penetrate complexity and make better decisions about everything from how to manage cities to how to solve confounding societal problems.

Why technology is important for healthcare

In today's healthcare environment, where physicians are often working with limited information and little time, the results can be fragmented care and errors that raise costs and threaten quality. Consider this:

- Primary care physicians spend an average of only 10.7 - 18.7 minutes face-to-face with each patient per visit.
- Information growth is exploding with medical information doubling every 5 years, but 81% of physicians spending less than 5 hours a week reading medical journals.
- An estimated 15% of diagnoses are inaccurate or incomplete.
- Complexity is increasing with an estimated 1.5 million errors annually in the way prescriptions are prescribed, delivered and taken.

As this Subcommittee knows, healthcare is one of the most data rich environments today. Much of this data is unstructured such as doctor notes, patient records, medical annotations, text from medical journals and clinical feedback. In fact, it is estimated that 80% percent of all healthcare data is unstructured. Advanced analytics combined with cognitive computing and natural language processing can help doctors efficiently access and make use of this ocean of information.

Let me give an example based on the explosion of genomic data available today. It's $99 to a thousand dollars depending on how you get it done to map your genome. It is possible in fields like cancer and ecology to map the genome of a tumor and get exactly the mutations in your specific tumor. It is also now possible to access voluminous information about treating these mutations. The problem is that sets of data are so massive that it is not practical for human beings to review and make use of them in treatment decisions. Cognitive systems could help solve some of these complex problems that need value unlocked and made understandable for humans on much shorter timelines. Insight timelines that can impact patient treatment and save lives.

Clinical decision support (CDS) software when used in healthcare also has the potential to provide medical information to clinicians that can be used to achieve individualized, evidence supported medicine.

Importantly, such a system would work in collaboration with healthcare professionals to provide evidence-based insights in a transparent, interactive manner so that the healthcare professional can drill down to see details on any relevant evidence.
When the software provides such transparency, making the clinical rationale evident to the user, the physician can make much deeper and informed decision about use of the insight. In this way, the software is "low risk", since it does not make any clinical decisions for the physician. The clinician remains the decision maker.

In such a scenario, the user would not be dependent on the system's evidence-based insights. Such a cognitive system becomes one of many tools available to the healthcare professional to transform effectiveness, efficiency and patient outcomes.

Lastly, in addition to the need to improve health outcomes, advances in technologies could help address disparities of access across the U.S.. Clinicians in remote and underserved locations could have access to the same evidence-based medical insights as those working in major metropolitan facilities to help inform their decisions.

The role of government

IBM is one part of a vibrant IT industry across the U.S. innovating in this area. IBM believes that Congress can contribute to these advancements by ensuring that there is a regulatory environment that encourages innovation while at the same time protecting the safety of individuals. IBM strongly supports the creation of a holistic health care life science ecosystem of solutions centered on the needs, and safety, of patients and consumers.

Innovation and improved patient safety are not inconsistent goals. In fact, I believe innovation can promote safe healthy environments and better tools to continuously promote learning and possibly improve care to reduce adverse events. Patient safety can actually be improved when regulatory structures promote innovation and shorten time-to-market.

In thinking about the appropriate role of the government to promote innovation and patient safety in healthcare, it is important to recognize that the current Food and Drug Administration (FDA) regulatory framework was largely developed during the decades before the rise of today's sophisticated IT technologies. This regulatory framework focuses on traditional discrete devices manufactured at a single site and physically shipped to distributors and users.

While some of these devices have contained software, they are frequently physical articles placed into commerce, they are modified relatively infrequently and often do not interact with multiple other devices provided by other parties. With the rise of networked ecosystems and even more sophisticated software, this paradigm does not encourage tomorrow's innovations.

The current approach is not a good fit for new technologies that operate within interconnected systems. The field of medical information technology is populated with multiple players, whose technology can be rapidly and iteratively improved through deep collaboration between IT providers and the clinical end-users. The resulting technologies are intended to aid clinical decision making rather than directly diagnose or treat patients.

Further, clear rules of the road enable a vibrant marketplace where developers, investors, businesses and consumers thrive knowing the path needed to bring their collaborations to market. Clarity encourages innovation and helps new innovators to enter the healthcare space. Clarity will encourage the development of life saving technologies to be brought to market in a timely manner.

One key area of health IT innovation that calls out for clarity is clinical decision support software. CDS does as it names says – provides clinical decision support – as one resource of many that clinicians can call upon, not solely rely upon, in their decision making process. As clinicians are not dependent on the output of sufficiently transparent CDS, the risk of harm to patients is low.

Currently, it is unclear whether such low risk CDS would be regulated. Congress has the prerogative to – and should - bring additional legislative clarity to the health IT environment now.

We urge Congress and the Administration to work together to clarify and recognize that in healthcare,

all software is not the same; there should not be a one size fits all regulatory approach for healthcare technology. Using the current medical device regulatory framework to determine if and how to regulate the diversity of potential healthcare IT software would be the proverbial case of trying to fit a square peg in a round hole.

One important step in the right direction is the Blackburn-DeGette bill.

IBM strongly supports this bipartisan legislation. By establishing greater regulatory clarity surrounding healthcare software, this bill will help foster technological innovation that will improve patient care.

This bill will encourage the continued development of evidence-based technologies that help doctors draw on far more evidence than any of them can possibly access on their own. It will refocus the the government's regulatory energies to software and devices that directly affect patients, without interfering with doctors' ability to draw on as much information as possible to inform their own expertise. This approach will ensure that U.S. consumers have access to the most innovative healthcare IT without being burdened by regulatory requirements that will not improve the safety of the products.

Safety and innovation are complementary concepts. To say that we must rely on the old framework would diminish our ability to evolve and innovate while better protecting safety. Any framework designed to protect patient safety in health IT should be risk-based, flexible and not stifle innovation. Existing IT safety and quality-related processes, systems, and standards should be leveraged for patient safety. Any additional standards needed could be set with collaboration between industry, government and interested stakeholders.

And, by creating an environment that encourages innovation, this legislative clarity would also help ensure that U.S. companies remain leaders in providing these technologies worldwide. IBM and

others, large and small, are poised to transform healthcare, this bill would provide the clarity and confidence to do so.

Conclusion

Innovations in health IT have great promise to tremendously improve the quality, cost-effectiveness, and patient experience of care.

With the growing needs of patients in our country and the opportunity for technology to provide the medical profession additional patient care insight, encouraging innovation in the United States is critical. If we can seize the opportunity, technological innovations can make medical practice, hospital care and every other aspect of healthcare more effective and efficient.

IBM encourages Congress and the Administration to work together to ensure a regulatory framework that promotes this innovation while respecting patient safety. We support the Blackburn-DeGette effort to do just that.

Thank you again for this opportunity to share IBM's view on such an important topic.

Mr. PITTS. The gentleman's time is expired.

Thank you, the chair recognizes Mr. Jarrin 5 minutes to summarize his testimony.

Make sure your mic is up. We had a little trouble hearing the last witness.

STATEMENT OF ROBERT JARRIN

Mr. JARRIN. Good morning, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee, earlier this year the Subcommittee on Communications and Technology——

Mr. PITTS. Is your light on?

Mr. JARRIN. Yes. There we go. I thought it was on, my apologies. Good morning, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. Earlier this year, the Subcommittee on Communications and Technology held hearings during the third week of March on health information technologies and innovations, including mobile medical apps. I was honored to have been invited to participate in the first of those hearings, and I am honored to be here today. Qualcomm Incorporated is number one global supplier of wireless chips and the leading inventor of 3G and 4G next generation wireless technologies. To date, Qualcomm's chip shipments surpass 11 billion. If a person is using a 3G or 4G device, Qualcomm's technology and ingenuity are being used.

Mobile technology continues to be the largest platform in history. Innovation continues to personalize health care as health apps are more available than ever via sophisticated smartphones and tablets that rely on powerful, ubiquitous 3G and 4G mobile broadband networks. In fact, according to MobiHealthNews Research, unique health apps now number over 33,000 in the U.S. After 2 years, the FDA delivered on its promise: A deregulatory and practical roadmap for the mobile health industry. This is significant for solo developers, garage entrepreneurs and established medical device manufacturers, such as Qualcomm's wholly-owned medical device subsidiary, Qualcomm Life. FDA has raised the bar and demonstrated how it can work with industry, be progressive, help speed innovation, and ensure public safety. But more is yet to come as broader issues linger which require the same light touch and flexible approach FDA has now demonstrated it is capable of adopting.

Additionally, the final Food and Drug Administration Safety Innovations Act, or FDASIA report due at year's end by FDA, ONC, and FCC should contain a proposed strategy and recommendations on an appropriate risk-based regulatory framework pertaining to health IT, including mobile medical applications. Qualcomm offers the following recommendations for consideration. Number one, as recommended by the FDASIA external working group report, FDA should utilize current program mechanisms that could enable innovations such as assessing exemption from good manufacturing practices for lower risk health IT, expediting guidance on health IT software and related matters, particularly FDA's 2014 proposed guidance development B list that includes medical device decision support software, medical device accessories, and general wellness products; continue to improve internal coordination on health IT software, and its regulatory treatment; and continue to utilize ex-

ternal facing resources to proactively educate the public about how policies and regulation impact health IT and mobile medical apps.

Number two, FDA, ONC, and FCC should address policy and regulatory deficiencies, ambiguity, and duplication in the final FDASIA report.

Number three, FDA should continue its commitment to consistency, predictability, and transparency by coordinating internal and external efforts through a single dedicated office of mobile health within FDA.

Number four, interoperability is a critical concern for reliable data exchange and secured health communications to and from mobile devices.

The FDA should collaborate closely with ONC in supporting the direct messaging exchange standards and the direct trust security and trust framework.

Number five, privacy data use rights and identity management issues have unique concerns in relation to mobile health devices. Close collaboration between the FDA, ONC, and FTC are essential to the establishment of consistent standards and requirements for industry health care providers and the public.

Qualcomm underscores the importance of FDASIA's work and encourages the involved agencies to utilize existing program mechanisms to enable innovation immediately. While they explore how to improve and modify existing frameworks, or if needed, develop recommendations for Congress to consider a new risk-based regulatory framework, what the public and industry don't need is a situation where innovation suffers as a result of regulatory confusion on health IT software, which is why existing program mechanisms are vital policy tools that can be employed promptly.

The end goal should be for a regulatory framework that allows new technology to flourish, promotes innovation, avoids regulatory duplication, and above all, protects patient safety. Thank you. I look forward to your questions.

[The prepared statement of Mr. Jarrin follows:]

Statement of
Robert Jarrin
Senior Director, Government Affairs
Qualcomm Incorporated

Before the
U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

Hearing on "Examining Federal Regulation
of Mobile Medical Apps and Other Health Software"

November 19, 2013

Summary

Mobile technology continues to be the largest platform in history. Innovation continues to personalize healthcare as health apps are more available than ever via sophisticated smartphones and tablets that rely on powerful, ubiquitous 3G and 4G mobile broadband networks.

After two years the FDA delivered on its promise: a deregulatory and practical roadmap for the mobile health industry. This is significant for solo developers, garage entrepreneurs and established medical device manufacturers such as Qualcomm's wholly-owned medical device subsidiary Qualcomm Life. FDA has raised the bar and demonstrated how it can work with industry, be progressive, help speed innovation and ensure public safety.

But more is yet to come as broader issues linger which require the same light-touch, flexible approach FDA has now demonstrated it is capable of adopting. The final FDASIA report due at year's end by FDA, ONC, and FCC should contain a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications.

Qualcomm offers the following recommendations for consideration:

1. As recommended by the FDASIA external working group report, FDA should utilize current program mechanisms that could enable innovation, such as:
   a. assess exemption from good manufacturing practices for lower-risk Health IT;
   b. expedite guidance on Health IT software and related matters, particularly those on its fiscal year (FY) 2014 Proposed Guidance Development "B List" including "Medical Device Decision Support Software", "Medical Device Accessories", and "General Wellness Products";
   c. continue to improve internal coordination on Health IT software and its regulatory treatment; and
   d. continue to utilize external facing resources to proactively educate the public about how policies and regulation impact Health IT and mobile medical apps.
2. FDA, ONC and FCC should address policy and regulatory deficiencies, ambiguities and duplication in the final FDASIA report.
3. FDA should continue its commitment to consistency, predictability and transparency by coordinating internal and external efforts through a single dedicated office of mobile health within FDA.
4. Interoperability is a critical concern for reliable data exchange and secure health communications to and from mobile devices. The FDA should collaborate closely with the ONC in supporting the Direct Messaging Exchange standard and the DirectTrust Security and Trust Framework.
5. Privacy, Data Use Rights, and Identity Management issues have unique concerns in relation to mobile health devices. Close collaboration between the FDA, ONC, and FTC are essential to the establishment of consistent standards and requirements for industry, healthcare providers and the public.

Qualcomm underscores the importance for Agencies to utilize existing program mechanisms to enable innovation immediately; while they explore how to improve and modify existing frameworks, or if needed, develop recommendations for Congress to consider a new risk-based framework. What the public and industry don't need is a situation where innovation suffers as a result of regulatory confusion in the health IT software space, which is why existing program mechanisms are vital policy tools that can be employed promptly. The end goal should be for a regulatory framework that allows new technology to flourish, promotes innovation, protects patient safety and avoids regulatory duplication.

Good morning, Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee. Earlier this year the House Energy & Commerce Committee, Subcommittee on Communications and Technology held a series of hearings during the third week of March on health information technologies and innovation, including mobile medical apps. I was honored to have been invited to participate in the first of those hearings, and I am honored to be here again today.

At the March hearing, my testimony centered around four core themes:

1) Mobile technology is the largest platform in history; it is at the center of our lives and touches every aspect of society;
2) The pervasiveness and costs of chronic disease in America, where almost one out of every two adults in the U.S. has at least one chronic illness[1];
3) Innovations are personalizing healthcare unlike ever before, such as mobile health apps that are available to hundreds of millions of people via sophisticated smartphones, tablets and devices that rely on powerful and ubiquitous 3G and 4G mobile broadband networks;
4) And a call for clarity from the Food and Drug Administration to finalize and release final guidance on mobile medical applications.

Over the past eight months, much has happened: mobile technology is as popular as ever with a recent TIME Invention Poll reporting that 71% of global consumers feel the mobile phone

[1] *See Chronic Diseases and Health Promotion,* Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) http://www.cdc.gov/chronicdisease/overview/index.htm.

is the most useful invention[2]; the Centers for Disease Control continue to affirm that as a nation, 75% of our health care dollars go towards the treatment of chronic diseases[3]; according to mobihealthnews RESEARCH, unique health apps for smartphone users in the U.S. continue to enjoy unprecedented growth accounting for over 33,000[4]; the FDASIA working group of external stakeholders and experts delivered strategy and recommendations to FDA, ONC and FCC, on the regulation of health IT and mobile medical apps; and after two years the Food and Drug Administration delivered on its promise to issue final guidance on mobile medical applications.

Overall, the final mobile medical apps guidance document is deregulatory and practical for the mobile health industry. In some respects it's quite an expansive document that seeks to liberalize the nimble and innovative mobile health apps industry, while ensuring patient safety. FDA makes the bold statement that "the majority of mobile apps on the market" are either not regulated outright or fall under "enforcement discretion." This is significant for solo developers, garage entrepreneurs and established medical device manufacturers such as Qualcomm's wholly-owned medical device subsidiary Qualcomm Life. FDA has raised the bar by demonstrating that it can work with industry, be progressive, help speed innovation and ensure public safety.

The issuance of this guidance did not come about without its share of controversy as many sides weighed in on whether FDA should even have the authority to regulate health IT software at all, let alone mobile medical apps. The hearings this Committee held earlier this year

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[2] *See The TIME Invention Poll*, TIME http://techland.time.com/2013/11/14/the-time-invention-poll/.
[3] *See Chronic Diseases and Health Promotion,* Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) http://www.cdc.gov/chronicdisease/.
[4] *See Consumer Health Apps By The Numbers*, mobihealthnews RESEARCH (2013).

illuminated the arguments for and against finalizing guidance and certainly played a role to expedite the delivery of the final guidance. But another development may have also played a role: the convening of the FDASIA external working group and its findings and recommendations.

In July of 2012 the Food and Drug Administration Safety and Innovation Act ("FDASIA") was signed into law, under which Section 618, titled "Health Information Technology" called for the Secretary of Health and Human Services, acting through the Commissioner of the FDA, and in consultation with the National Coordinator for Health Information Technology (ONC) and the Chairman of the Federal Communications Commission (FCC), to post within 18 months "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." Section 618 of the Act allowed the Secretary to convene a working group of external stakeholders to provide input for a final report to be developed by FDA, ONC and FCC.

In total, thirty-two expert stakeholders (including Qualcomm) served as members of the FDASIA external working group who represented patient advocates, healthcare providers, start-ups, health plans, venture capital investors, information technology vendors and ex-officio federal officials. The recommendations by the external working group were delivered to the three agencies on September 4, 2013, and included the unequivocal statement that: "FDA should expedite guidance on HIT software, mobile medical apps and related matters."

Three weeks later on September 25, 2013, the FDA issued final guidance on mobile medical apps. The final guidance was a marked improvement over the original draft guidance issued on July 21, 2011. Final guidance included two new appendices that help clarify which apps are not medical devices and those apps that will not be regulated under the Agency's "enforcement discretion," (i.e., apps that FDA will choose not to regulate even though they may meet the definition of a medical device but pose such a low-risk to the public it makes little sense to impose regulation). By doing so, FDA expressed that it will not actively enforce any requirements it typically would obligate under the law. To strengthen this point, FDA provides several pages of examples of mobile apps that fit in this category, including:

- Medication reminders are currently regulated as Class I medical devices, that are exempt from 510(K) and good manufacturing practices. FDA will no longer enforce any requirement for manufacturers of these types of medication reminders. It means manufacturers and specification developers developing medication reminders will not have to register with FDA, list those devices with FDA or conform to general controls as required of manufacturers by FDA, regardless of platform (whether mobile or other). This is an important development going forward as a number of wireless health companies, some of which are Qualcomm Life partners, have brought medication reminders to market including WellDoc, Vitality, Vocel, MedMinder, and CleverCap, to name a few.
- Mobile medical apps that allow a user to collect (electronically or manually entered) blood pressure data and share these data through e-mail, track, trend or upload them to a PHR or EHR. Such an app is not regulated through enforcement discretion.

- Mobile medical apps intended for medical uses that utilize a mobile device's built in camera or connected camera for documenting and transmitting pictures of medical conditions to supplement verbal descriptions in consultations with healthcare providers or between providers – not regulated under enforcement discretion.
- Mobile medical apps that provide patients with simple tools to organize and track health information without providing recommendations to alter or change a prescribed treatment or therapy on specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to log, track, or trend events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease-management plan – not regulated under enforcement discretion.
- Mobile medical apps that serve as a checklist of symptoms that provide possible medical conditions and offer advice on when to consult a healthcare provider – not regulated under enforcement discretion.
- Mobile health apps intended to enable patients to interact with PHR systems or EHR systems – not regulated under enforcement discretion.
- Medical calculators (i.e., BMI, total body water/urea volume of distribution, mean arterial pressure, Glasgow Coma Scale score, Apgar score, NIH stroke scale, and delivery date estimators), some of which were listed in the original draft guidance as regulated mobile medical apps – not regulated under enforcement discretion.

Indeed there are dozens of references throughout the final guidance that bring much needed clarity on what it is, what is not, and what will not be regulated.

FDA should be commended for what this guidance has provided, as well as for what the Agency did as a result of its release. FDA has created a new public facing webpage on mobile medical apps with informational links for the public and developers; on a public call hosted by FDA and timed with the release of the guidance, Dr. Jeffrey Shuren the FDA's Center Director of the Center for Devices and Radiological Health, alluded to the creation of a "special team under CDRH senior management" that would be tasked with answering public inquiries submitted to a newly created FDA mobile medical apps e-mail address for questions (mobilemedicalapps@fda.hhs.gov); and lastly, the FDA posted a list of regulated mobile medical apps that serve as examples of devices which FDA has cleared or approved since 1997.

These pronouncements and actions by FDA, taken in part or as a whole, are good for the industry, great for developers and excellent for the people who stand to utilize these novel devices to learn, track and improve upon their health and wellbeing. Through the release of this helpful document, FDA has demonstrated its ability to ensure predictability, consistency and transparency in a radically changing technological age. However, it's important to note that more is yet to come as issues linger which require the same light-touch, flexible approach that FDA has demonstrated it is capable of adopting.

Qualcomm offers the following recommendations for consideration:

1. As recommended by the FDASIA external working group report, FDA should utilize current program mechanisms that could enable innovation, such as:
   a. assess exemption from good manufacturing practices for lower-risk Health IT[5];
   b. expedite guidance on Health IT software and related matters, particularly those on its fiscal year (FY) 2014 Proposed Guidance Development "B List" including "Medical Device Decision Support Software", "Medical Device Accessories", and "General Wellness Products"[6];
   c. continue to improve internal coordination on Health IT software and its regulatory treatment; and
   d. continue to utilize external facing resources to proactively educate the public about how policies and regulation impact Health IT and mobile medical apps.
2. FDA, ONC and FCC should address policy and regulatory deficiencies, ambiguities and duplication in the final FDASIA report due at year's end.
3. FDA should continue its commitment to consistency, predictability and transparency by coordinating internal and external efforts through a single dedicated office of mobile health within FDA.
4. Interoperability is a critical concern for reliable data exchange and secure health communications to and from mobile devices. The FDA should collaborate closely with the

[5] "HIT" as defined according to the FDASIA External Working Group in the September 4, 2013, final "Committee Report," (*Defining Characteristics of What Should be Included as HIT/ "Eight Key Dimension of HIT"*).
[6] *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm.

ONC in supporting the Direct Messaging Exchange standard and the DirectTrust Security and Trust Framework.[7]

5. Privacy, Data Use Rights, and Identity Management issues have unique concerns in relation to mobile health devices. Close collaboration between the FDA, ONC, and FTC are essential to the establishment of consistent standards and requirements for industry, healthcare providers and the public.

The final FDASIA report due at year's end by FDA, ONC, and FCC should contain a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications. "A risk-based regulatory framework" can be interpreted to mean an existing regulatory framework – or – a new one to be created. Qualcomm's recommendation would be for FDA, ONC and FCC to consider both tracks: utilize existing program mechanisms that could enable innovation immediately; while they explore how to improve and modify existing frameworks, or if needed, develop recommendations for Congress on a new risk-based framework. It is essential that these agencies recognize the growing importance of managing risk at a systems level and that any comprehensive regulatory scheme should take into account existing solutions when contemplating future innovations. The end goal should be for a regulatory framework that allows new technology to flourish, promotes innovation, protects patient safety and avoids regulatory duplication.

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[7] *See ONC Partners with Two Health Information Exchange Governance*, Office of the National Coordinator for Health Information Technology (ONC), Health IT Buzz Blog (April 2013) http://www.healthit.gov/buzz-blog/health-information-exchange-2/onc-partners-health-information-exchange-governance-entities/.

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What the public and the industry don't need is a situation where innovation suffers as a result of regulatory confusion in the health IT software space, which is why FDA's existing program mechanisms are vital policy tools that can be employed immediately. Any new framework regardless of how well intentioned it may be, will take time, intense legislative action, rulemaking, subsequent implementation, a modicum of uncertainty and potentially millions in taxpayer dollars to establish. Wasting time through uncertainty only harms innovation and that's something we should all try to avoid.

About Qualcomm

Qualcomm Incorporated is the number one global supplier of wireless chips, and the leading inventor of wireless technologies. To date, Qualcomm's chip shipments surpass 11 billion. Qualcomm is a world leader in 3G, 4G and next-generation wireless technologies. If a person is using a 3G or 4G device today, Qualcomm's technology and ingenuity is being used.

Qualcomm Life (QCL), a wholly-owned subsidiary of Qualcomm Incorporated, is a medical device manufacturer focused on producing medical device data systems. QCL has developed the 2net™ Hub, 2net™ Mobile, and 2net™ Platform. The 2net Hub, connects medical devices to the 2net Platform's data center and is a compact "plug-and-play" mobile broadband gateway that supports Bluetooth, Wi-Fi, and ANT+ local area radio protocols. 2net Mobile is a software module that enables mobile computing devices such as mobile phones and tablets to serve as gateways to the cloud-based 2net Platform. The 2net™ Platform reliably captures and delivers medical device data to integrated portals or databases. In April 2013, QCL acquired HealthyCircles™, a care coordination platform that is an enterprise software-as-a-service (SaaS) solution designed to connect care teams and deliver transitional care, telehealth and exception-based care management solutions. As a care coordination and management platform company, HealthyCircles™ provides Enterprise clients with private-label branded web, mobile and multi-lingual solutions and services that address hospital readmission reduction, care transitions, home health monitoring and management, accountable care organizations (ACO) and patient-centered medical homes (PCMH).

The Qualcomm Life Fund was established in 2011 with the amount of $100 million of funding with the goal of accelerating global wireless health services and technology adoption. The Qualcomm Life Fund specifically focuses on investing in venture-backed wireless health start-ups that will help accelerate the 2net™ Platform commercialization.

The Qualcomm Foundation, which Qualcomm established in 2010, is dedicated to developing and strengthening communities worldwide. Specifically, the Qualcomm Foundation focuses it philanthropic efforts on helping create and sustain educated, healthy, culturally vibrant communities in regions around the globe. As sponsor of the Qualcomm Tricorder X PRIZE competition, the Qualcomm Foundation is proud to support the discovery of innovative mobile solutions that will contribute to the advancement of healthcare and diagnostics.

Qualcomm's Wireless Reach initiative is a strategic program that brings wireless technology to underserved communities globally. Wireless Reach invests in projects that foster entrepreneurship, aid in public safety, enrich teaching and learning, improve environmental sustainability and enhance the delivery of healthcare. Wireless Reach has 88 projects in various stages of development in 34 countries (over 30 projects are related specifically to healthcare).

Qualcomm includes Qualcomm's licensing business, QTL, and the vast majority of its patent portfolio. Qualcomm Technologies, Inc., a wholly-owned subsidiary of Qualcomm Incorporated, operates, along with its subsidiaries, substantially all of Qualcomm's engineering, research and development functions, and substantially all of its products and services businesses, including its semiconductor business, QMC.

Mr. PITTS. The chair thanks the gentleman and I any recognize Dr. Lichtenfeld, 5 minutes for opening summary.

STATEMENT OF J. LEONARD LICHTENFELD

Dr. LICHTENFELD. Thank you, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. I am Dr. Len Lichtenfeld. I am Deputy Chief Medical Officer for the American Cancer Society, and I thank you all for the opportunity to testify before you today.

Software applications play an increasingly integral role in the care of patients, including and especially patients with cancer. So I applaud this committee's bipartisan attention to providing a proper level of oversight for these products.

As we all know, cancer care has changed significantly in the past 40 years when it might have been enough for a physician to manually assess a tumor size, determine the appropriate diagnosis, and the recommended treatment for a patient with cancer. We are now moving into an era where everything from sending patient appointment reminder emails to analyzing genetic tests are all done using software, and software applications have increased our ability to quickly and accurately diagnose patients and develop the most effective treatment plans as mentioned earlier today.

Continued innovation in this space is an urgent priority for cancer patients, survivors, their families, loved ones, and of course, their health care professionals. At the same time, the power of software applications to improve patient care must be tempered by potential dangers that come with any new medical intervention. We consider it unethical to administer new drugs as part of a patient's treatment without first understanding both the safety and the efficacy of those medications, and similarly, we need to understand the safety and efficacy of integrating software applications directly into patient care.

In terms of the appropriate calibration of oversight for software applications, you will find nearly universal agreement, the lowest products do not merit FDA oversight, while high risk ones do. The real challenge lies in how to create oversight for the space in between that may include clinical software, mobile apps, similar products.

Rather than commenting on specific proposals, I would like to offer several broad design criteria for your consideration. First, and foremost, patient safety and privacy are paramount to all of us. It is the first duty of medical professionals, the relevant oversight agencies and policymakers to ensure that patients are not subjected to dangerous, ineffective, or misleading treatment and that their information is secure.

Second, any information oversight system should be fluid. Technology is advancing at a speed challenging our ability to provide effective oversight. And some technology in use today was, as we know, almost unheard of 5 years ago, and so any new oversight structure should not be so rigid that it cannot quickly adapt to new realities.

Third, details matter. The changes are enacted to create new categories of medical software applications with differing levels of

oversight, then the definitions of those categories must be very clear and not create loopholes, ambiguities, or unintended consequences.

Fourth, focus the solution on the actual problem. Innovation software mobile apps can be promoted through regulatory certainty and the relief of regulatory burden on software sectors where it is not appropriate. This may be possible with narrower policy changes aimed at targeted sets of software rather than the full spectrum of software and mobile apps.

In closing, let me reiterate. The innovative new software will be crucial to making progress against cancer, and ensuring patient safety. We need a risk-based oversight paradigm for this software that does not impose a heavy regulatory hand that might otherwise stifle innovation. But we must never allow the pursuit of innovation to displace patient safety and privacy as our primary considerations. Wherever software is involved directly in patient health, oversight is not only appropriate, but it is necessary. I thank you again for the opportunity to share our views and I look forward to your questions. Thank you.

[The prepared statement of Dr. Lichtenfeld follows:]

Testimony Summary of
J. Leonard Lichtenfeld, MD, MACP
Deputy Chief Medical Officer, American Cancer Society

Before the U.S. House Energy and Commerce
Subcommittee on Health
"Examining Federal Regulation of Mobile Medical Apps and Other Health Software"
November 19, 2013

Progress in cancer has been significantly aided through the use of computing and software applications which have increased our ability to quickly and accurately diagnose patients, predict disease trajectory and develop the most effective treatment plans. With this promise, the development of ever more powerful software applications is an urgent priority for cancer patients and survivors.

Our optimism for the power of software applications to improve patient care, however, must be tempered by the potential dangers that come with any new medical intervention. We would consider it unethical to administer new drugs or devices as part of a patient's treatment without first understanding the safety and efficacy of these interventions, and similarly we need to understand the safety and efficacy of integrating software applications directly into patient care.

You will find nearly universal agreement that low-risk products do not merit FDA oversight, while high-risk ones do. The real challenge lies in how to create an oversight paradigm for the space in between that may include clinical software, mobile apps and other similar products. Rather than commenting specifically on the various proposals under consideration, the following broad design criteria should be considered.

Patient safety and privacy are paramount. Medicine is performed in the service of patients and it is the first duty of medical professionals, Congress, and the relevant oversight agencies to ensure that patients are not subjected to dangerous, ineffective, or misleading treatment, and that their information is secure.

Any oversight system should be fluid. Technology is advancing at a speed that challenges our ability to provide effective oversight. Some of the technology in use today was almost unheard of five years ago, so any new oversight structure should not be so rigid that it cannot quickly adapt to new realities.

Details matter. If changes are enacted to create new categories of medical software applications with differing levels of oversight, then the definitions of those categories must be very clear and not create loopholes, ambiguities, or unintended consequences.

Focus the solution on the actual problem. Innovation in software and mobile apps can be promoted through regulatory certainty and the relief of regulatory burden on software sectors where it is not appropriate. This may be possible with narrower policy changes aimed at targeted sets of software rather than an entirely new paradigm for the full spectrum of software and mobile apps.

In closing, software will be crucial to making progress against cancer and ensuring patient safety. We need a risk-based oversight paradigm for this software that does not impose a heavy regulatory hand that might stifle innovation, but we must never allow the pursuit of innovation to displace patient safety and privacy as our primary considerations. Wherever software is involved directly in patient health, oversight is not only appropriate, but necessary.

Statement of
J. Leonard Lichtenfeld, MD, MACP
Deputy Chief Medical Officer
American Cancer Society

Before the U.S. House Energy and Commerce
Subcommittee on Health
Hearing on
"Examining Federal Regulation of Mobile Medical Apps and Other Health Software"
November 19, 2013

Chairman Pitts, Ranking Member Pallone and Members of the Subcommittee, I am Dr. Leonard Lichtenfeld, deputy chief medical officer for the American Cancer Society. On behalf of the Society, I want to thank you for the opportunity to testify at today's hearing. The Society is a nationwide, community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer through research, education, advocacy, and service. The Society, operating through its national office and 12 geographic divisions throughout the United States, is the largest voluntary health organization in the United States.

Health information technology (HIT), software programs and mobile applications (apps) play an increasingly integral role in the care of patients, so I applaud this Committee's bipartisan attention to the question of providing the proper level of oversight. In addition to my role at the Society, I am involved with the eHealth Initiative and the Bipartisan Policy Center, where we are exploring the promise of technology for improving patient health and are working together to develop the policies needed to ensure continued progress in this direction. I am pleased to share with you my perspectives gleaned from these ongoing conversations as well as the unique cancer lens on these issues.

Cancer is the second leading cause of death in the United States, taking the lives of more than 575,000 Americans every year. Advances in cancer prevention, detection and treatment over the past 40 years have led to improved outcomes and even curative treatments for many types of cancers. That progress has been significantly aided through the use of computing and software applications. New applications will undoubtedly play an increasing role in cancer prevention, detection and treatment. While years ago it might have been enough to assess tumor size, histology and location within the body to determine the appropriate diagnosis and treatment for cancer, we are moving to an era of personalized medicine where large panels of genes are routinely assayed and processed using algorithms to determine prognosis and appropriate treatment. Imaging hardware paired with the latest software can now detect differences in MRIs or tissue samples that may not be visible to the human eye. These new imaging techniques can

also be performed in less time than through traditional human methods. The explosion of computing power has increased our ability to quickly and accurately diagnose patients, predict disease trajectory and develop the most effective treatment plans. With this promise, the development of ever more powerful HIT and software applications is an urgent priority for cancer patients and survivors.

Our optimism for the power of HIT and software applications to improve patient care, however, must be tempered by the potential dangers that come with any new medical intervention. We would consider it unethical to administer new drugs or devices as part of a patient's treatment without first understanding the safety and efficacy of these interventions in treating a specified disease. In the same manner it would be unacceptable to integrate software applications directly into patient care, whether diagnostic, prognostic, or therapeutic, without first understanding the safety and efficacy of those applications or the implications for patient privacy. A determination of safety and efficacy requires some form of appropriate oversight.

The spectrum of HIT and software applications, which ranges from the billing software used in the administration of a doctor's office to the software that is actively controlling a respirator sustaining a patient's life, merits different levels of oversight. The idea of risk-based oversight is widely embraced by multiple sectors within the medical community and shares bipartisan support. You will find nearly universal agreement that scheduling and billing software does not merit Food and Drug Administration (FDA) clearance and that diagnostic imaging software does merit FDA oversight. The real challenge lies in creating the risk-based paradigm to calibrate oversight for everything in between.

The types of applications that fall into this zone of uncertainty could include, for example, clinical decision support or mobile apps that guide patient self-therapy. For each of these examples there are instances where the application in question could pose little risk, or instances where it could pose grave risk. Clinical decision support that uses data from electronic health records to calculate BMI and suggests that a physician discuss weight loss strategies with an overweight patient is very different than decision support that incorporates several dozen variables ranging from histology reports, genetic tests and imaging reports to deliver a cancer diagnosis, prognosis and suggested treatment protocol. A self-therapy mobile app may be relatively harmless if it is suggesting exercise to improve fitness, but it may pose serious risk if it is recommending insulin dosing. In these cases, creating definitions for broad categories of apps does not necessarily provide adequate illumination of the risk posed by individual products within those categories, so someone must be the umpire for individual cases.

I was recently part of a Bipartisan Policy Center initiative that examined what a risk-based regulatory paradigm for HIT might look like that would involve three different categories of oversight. The current FDA guidance has also endorsed a risk-based paradigm with three categories of oversight for HIT, software and mobile apps, one category clearly subject to strict FDA regulation, one subject to regulatory enforcement discretion based on risk, and one category not subject to FDA oversight. Lastly, bipartisan legislation introduced by several members of this committee has similarly proposed a multi-tiered model for a risk-based oversight paradigm. These three models use different approaches including statutory changes, sub-regulatory guidance, and partnership with professional organizations. Regardless of the

approach taken, I would like to offer several considerations that must not be overlooked in the design of a new model.

Patient safety and privacy are paramount. Medicine is performed in the service of patients and it is the first duty of medical professionals, Congress, and the relevant oversight agencies to ensure that patients are not subjected to dangerous, ineffective, or misleading treatment, and that their information is secure. Wherever medical software or mobile apps are involved in diagnostic, prognostic, or therapeutic decisions, oversight is not only appropriate, but necessary.

Any oversight system should be fluid. Technology is advancing at a speed that challenges our ability to provide effective oversight. Some of the technology in use today was almost unheard of five years ago. While it is possible to create systems to address today's technologies, any oversight structure should not be so rigid that it cannot quickly adapt to new realities.

Details matter. If changes are enacted to create new categories of medical software applications with differing levels of oversight, then the definitions of those categories must be very clear and not create loopholes, ambiguities, or unintended consequences. Many software applications contain multiple functions, and each individual function in isolation could conceivably fit into a different regulatory category, so clarity about where in the regulatory scheme these multi-functional applications fit is needed. Furthermore, software is currently considered a device by the FDA, so without changing the existing paradigm by redefining devices in statute to explicitly exclude software, new categories may simply cause confusion rather than clarity. In other words, creating a new category of "Software that is not a component of a device…" could be seen as a circular definition given that software is currently seen as a type of device.

Focus the solution on the actual problem. Innovation in HIT, software, and mobile apps can be promoted through regulatory certainty and the relief of regulatory burden on sectors of HIT where it is not appropriate. (As noted above, however, this cannot take precedence over patient safety.) Targeted changes aimed at narrow sets of software and mobile apps may provide the desired regulatory certainty while lowering the chance of unintended consequences rather than creating an entirely new paradigm for the full spectrum of HIT, software and mobile apps.

Lastly, I suggest that a new model of oversight be well-informed by the health IT regulatory strategy report commissioned by the Food and Drug Administration Safety and Innovation Act (FDASIA) that is being prepared jointly by the FDA, the Office of the National Coordinator for Health Information Technology, and the Federal Communications Commission. Like you, I will be eager to read the findings when it is issued in the next few months.

Conclusion

In closing, I would like to reiterate the vital role of HIT, software programs, and mobile apps in making progress against cancer and ensuring patient safety. There is broad recognition that not all software applications pose the same risk to patients; therefore, there needs to be a risk-based paradigm for calibrating the appropriate oversight. We do not want a heavy regulatory hand to stifle innovation, but we must never allow the pursuit of innovation to displace patient safety and

privacy as our primary considerations. When software or mobile apps have the potential to affect patient health, someone must be on the watch.

Thank you again for the opportunity to share our views.

Mr. PITTS. The chair thanks the gentleman. That concludes the opening summaries. We will now begin questioning. I will recognize myself 5 minutes for that purpose.

Mr. Lemnios, so why, in your opinion, is it important that Congress address regulating medical apps?

Mr. LEMNIOS. I am sorry?

Mr. PITTS. Why is it important that Congress address regulating medical apps in your opinion.

Mr. LEMNIOS. We think the key issue here is one of clarity and it goes back to comments that several Members made in their questions in the opening statements. For the private sector to make investments in developing new technologies and transition those technologies, that involves decisions on partnerships, it involves strategic decisions on where we will make those investments, all of which must be framed——

Mr. PITTS. Pull the mic a little closer, sir. They say they are having trouble hearing.

Mr. LEMNIOS. Let's try this.

Mr. PITTS. There you go, that is good.

Mr. LEMNIOS. You know, you guys really ought to get an IBM mike. This doesn't say IBM.

Mr. PITTS. All right. We will start over.

Mr. LEMNIOS. The question was why should Congress, why should this committee make a recommendation and pursue this? Look, I think it is an issue of clarity, and in fact, that will help our business decisions, and I think it will help decisions of small innovators as well. And that is really what we want. Not to compromise patient safety. But to build that environment that encourages innovation in this field.

Mr. PITTS. Thank you. Mr. Marchlik, do you think the FDA has the regulatory structure to appropriately regulate medical apps?

Mr. MARCHLIK. I believe that they have certain structures that they have been able to use for embedded software very effectively. Where we have questions is around clinical software, where implementation and use of the software is just as important as the development, and there what we see is that FDA doesn't have the oversight models necessary to ensure patient safety across that continuum.

Mr. PITTS. Mr. Bialick, do you think that the regulation of medical devices is best addressed through agency guidance, legislation, or a combination of both?

Mr. BIALICK. I think it is most likely a combination of both. I think in hearing Dr. Shuren's testimony that there is—it is quite clear that there is an effort within FDA to do the right thing, to figure out how to fix the process. But I also think that it is important to note that through the FDASIA working group that he mentioned and so did Mr. Jarrin mention, the external working group as well as those that will make the report, I guess, in the first quarter of next year, there were a number of issues that were identified by not only stakeholders that were part of that external group, but actually representatives from the agencies, FDA, FCC and ONC that identified that there were some issues that got, like we said before, broken at the level of the written law. And if that is the case, then you are very well going to need a hybrid of both.

Mr. PITTS. Mr. Lemnios, one of the main themes in this hearing is how quickly technology is evolving. Some may argue that because the industry is changing so much so quickly, we should just continue to release guidances. Why do you think we should address this legislatively, and how do you suggest we incorporate enough flexibility to make sure the agency is equipped with the flexibility to adapt to this evolving industry?

Mr. LEMNIOS. So that is a tension in the dialogue. The tension is how much flexibility and how much certainty will there be in this environment? And I think what the bill has done, and I would compliment the Congressman, the Representative for drafting this—what the bill has done it has laid out three imperatives that, in our view, sort of lay the structure. Whether there is direct change in function, or structure of the body, whether there is an involvement of a health care provider, and whether the software is marketed to individuals or to health care providers. I think those are three key elements that you could build on.

Now, there is going to be a lot of discussion about each, there will be a lot of discussion, does this particular software fit under this category or that? But I think the basic structure that was put in place really provides a way to build on this.

Mr. PITTS. Let me ask each of you to respond to this question. We will start at the other end. Dr. Lichtenfeld, can you discuss the impact health IT can have on the personalization of medicine as well as the potential to lower medical cost?

Dr. LICHTENFELD. Obviously, it is a world that I live in in a lot of different ways, and there is no question whatsoever that health information technology is going to have a huge impact on patient care, is going to have a huge impact on directing personalized medicine, precision medicine, and making sure that it works right is critically important. We have to have the certainty that we need not only as health professionals, as patients. We need to make certain just as we do with our medications, that what people say something is going to do, is, in fact, going to do it.

Mr. PITTS. OK.

Dr. LICHTENFELD. We are adjourning a discussion with the early part of that discussion as we are here today with obviously much more to come in the not too distant future.

Mr. PITTS. Mr. Jarrin.

Mr. JARRIN. Health IT has and will continue to have a huge impact on America, especially things like cost savings. I would only point out that 330 million subscriptions in America right now for mobile devices, yet one out of two adults according to the CDC—one out of almost—one out of two adults in America, has at least one chronic illness and chronic disease is about 75 percent of our health care cost. I think will you start to see that go down as the ubiquity of health IT continues.

Mr. PITTS. Briefly, Mr. Lemnios.

Mr. LEMNIOS. Again, I view the impact both from the private—on the patient side, but also on the provider side. If I look at the enormous growth in information that a health care provider can access, a doctor can access, software that translates that complexity into something that provides some insight is going to have a sig-

nificant value. So in fact, it will, I think in both cases, there will be a significant improvement.

Mr. PITTS. Mr. Bialick.

Mr. BIALICK. I absolutely do believe health IT will have a huge impact on the personalization of medicine. We often talk about personalized medicine like it is a single thing, like we can go buy personalized medicine, but personalized medicine is the consequence of a health technology-enabled health care system where we are able to communicate between devices, between providers, between patients, and have that information created in a way that it is valuable to the individual at the point of care.

Mr. PITTS. Mr. Marchlik.

Mr. MARCHLIK. Yes, I would agree that the will and the data is there and the opportunities to find applications which actually can unlock that data and help with personalization.

Mr. PITTS. Thank you. My time is expired. The chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman. My questions are of Dr. Lichtenfeld. You note in your testimony that it is necessary to ensure that any new definitions enacted into statute be very clear and not create loopholes, ambiguities or unintended consequences. You also note that many software applications contain multiple functions and each individual function in isolation could conceivably fit into a different regulatory category. So clarity is needed about where in the regulatory scheme these multifunctional applications fit. Those points argue, at least for me, that this is not an area that could be easily addressed through legislation. In FDA's recently issued guidance, it appears to me to have been well received by many stakeholders who have indicated that it provide the necessary clarity to allow innovations to flourish. As you say in your testimony, any oversight structure should not be so rigid that it can't quickly adapt to new realities.

So my questions are: Are you concerned that legislation will not provide the requisite flexibility here? Do you agree that guidance is an appropriate way to oversee this kind of technology?

Dr. LICHTENFELD. Far be it for me to say to Congress whether or not you are able to legislate something. That is in your purview, and I understand that the America Cancer Society understands that. I mentioned a moment ago there are substantial conversations that are currently ongoing, and I believe that this legislation begins the process within the legislative branch, but certainly within the private sector and within the advocacy sector, and with interested parties, we have had a lot of discussions surrounding these issues.

So our concern is that the FDA guidance meets a need at the present time that listening to the testimony today reinforces, in my opinion, that they have the flexibility and the direction that we need today. But we are going to be having a different conversation even within the next several months. And that definitions do matter, not that they are not appropriate, not that they are not important, but they do matter. And putting something into legislative language today to codify something when even in a couple of months we may be having a different discussion, or a more informed discussion among all of the parties, both governmental, leg-

islative, private sector, advocacy, this may not be the right time for us to do that as opposed to, number one, seeing how the FDA guidance works, and number two, listening to the reports and discussions that we are going to be having as I mentioned in the not too distant future, hopefully.

Mr. PALLONE. Well, thank you. Let me also say, FDA indicated on the first panel that the Blackburn bill would exempt from all FDA oversight such apps as radiation therapy planning software, and mammography detection software, to name a couple. I have no doubt that the sponsors of the bill had no intention of exempting such apps from oversight, but these examples generally illustrate the difficulty deriving the perfect language for legislation. Would you be concerned about legislation that permanently removed FDA's jurisdiction over certain types of software that might ultimately pose patient safety risks?

Dr. LICHTENFELD. Well, it is not a question so much of opposing the legislation, but making sure that we understand the potential risk of unintended consequences and definitions, as I mentioned, definitions matter. Getting those definitions right in legislative language is an art. It is difficult. It has to be done properly. If we don't do it properly, we do run the risk of having—we do believe we have issues of oversight difficulties and what we would call unintended consequences so the definitions are critically important.

Mr. PALLONE. You make another important point in your testimony that we are still awaiting the report that Congress requested in last year's FDASIA legislation from FDA, from the Office of the National Coordinator for Health Info Technology and the FCC. So do you agree that any legislation that we consider here should be informed by that report?

Dr. LICHTENFELD. I do. As you are well—as you are probably aware, there have been several reports, one from the Bipartisan Policy Center that came out recently, another one from the Office of National Coordinator. We are awaiting the report from the working group as was mentioned. And I think that in the—what I think is an appropriate place, is to say we need to have that information. We need to be able to understand that information. We need to have the input of all of the relevant stakeholders before we advance a legislative remedy—before we advance the legislative remedy, I should say.

Mr. PALLONE. All right. Thanks a lot. And Mr. Chairman, I am not convinced there is a problem that needs to be fixed here, and if there is, that it should be addressed by such a broad piece of legislation that virtually rewrites FDA's oversight of what is a fast-moving technology. But I think it is important that we had this hearing today. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman. I now recognize the gentlelady from Tennessee, Ms. Blackburn, for 5 minutes of questions.

Mrs. BLACKBURN. Thank you, Mr. Chairman. You all have been very patient with us, and I hope I don't take my whole 5 minutes. How is that for starters?

Mr. Marchlik, three quick questions, and thank you for your testimony. I want you to just kind of give a brief concise overview, the difference between health IT, and medical devices, why they need

to be approached differently. You argued in your testimony that the FDA is not well-suited for regulating the software. I want you to expand a bit on why, and then going back to the FDASIA work group recommendations that were presented to the ONC policy committee earlier this fall, I want to know what you thought about that.

Mr. MARCHLIK. Thank you. I think it is important that we believe that the legislation and we agree that the FDA would still be well-suited to regulating certain types of software. Some of the applications that we expect would still be regulated would be, for example, are perinatal care monitoring type of software. Some of our cardiology products would meet those definitions, would still be regulated by the FDA.

What I testified to and what we believe is that in a clinical software space, it is not just a development. And it is not just a manufacturer, which has standard, is regulated by the FDA, but it is implementation and use. We deliver products that actually require input, and configuration of the practice of medicine for it to actually be fully functional. And the FDA oversight doesn't extend that far. What we would be looking for is the new oversight model which would be able to expand and address that whole segment of that.

On the FDASIA report, I believe that a lot of the findings that came out of FDASIA report were consistent with the BPC report. Maybe, I think it is interesting is that we talk about the need for legislation or not. Partly, I think what happened is that in parts of the report, they were constrained because the only oversight was FDA oversight, and therefore, if there was a need for oversight it pointed to FDA versus nothing else. And there is a gap there and that is where we think the bill was very good about laying out that there should be an alternative for type of clinical software.

Mrs. BLACKBURN. Excellent. Thank you, for that. Mr. Bialick, does the FDA currently require changes to existing drugs or devices on the market to go through an FDA review process before they go to the patients?

Mr. BIALICK. So you are asking if there are changes to existing devices?

Mrs. BLACKBURN. Yes.

Mr. BIALICK. As someone who has never put a device through the process, I unfortunately can't answer that.

Mrs. BLACKBURN. All right. OK, let me move on then. I was asking that in relation, Dr. Shuren, during his answer to Congressman Lance said that patches, or updates, to the apps that could improve or harm patient safety would not have to go through the FDA approval process. So does that concern you?

Mr. BIALICK. The question in my mind is really how those errors or how those bugs are coming to people's attention. I think that what really we should be trying to do here is foster an environment where there is a transparent nature, a combination of punitive and non-punitive mechanisms and levers that would allow both vendors, maybe through the protections of something like patient safety organizations as well as providers, and really patients to have a way to redress their grievances to say there is a problem. We want to figure out what it is, and fix it as fast as possible. Now,

depending on if this is the world of the SOFTWARE Act or if this is the world of FDA now, whether that goes through the FDA, whether that goes back through a certification process, whatever it is, I think just the real take-away there is that we need to have a system of transparency so if there are patches we know why they were needed.

Mrs. BLACKBURN. OK, so I guess what you are saying that enforcement discretion rather than certainty, could have some unintended consequences on patient safety, especially with the very delicate patients that you all focus upon, is that fair?

Mr. BIALICK. I think in certain circumstances, absolutely.

Mrs. BLACKBURN. OK, thank you. I yield back.

Mr. PITTS. The chair thanks the gentlelady. I now recognize the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman, I appreciate it very much. In the 1970s, Congress wrote the statute giving the FDA the authority to regulate medical devices. As is often the case, technology will outrace the law, and government is forced to use outdated laws to deal with emerging situations. When the Medical Device Statute was created, we did not have personal computers, cell phones, the Internet, or cloud computing. Yet, these things are part of our daily lives. We need to modernize the law in my opinion, to provide clarity to the FDA, and the medical software industry, on the regulatory framework for their respective industries. And I want to ask Mr. Marchlik, a question, Mr. Marchlik. You have suggested in your testimony that different types of health IT should be regulated differently. Isn't that exactly what the FDA is doing using their discretion?

Mr. MARCHLIK. I believe that what they have attempted to do within the boundaries of the current legislation is to use enforcement discretion to carve out those products which they are not going to actively enforce. I think that what is needed is actually to take a fresh look at that, and also to expand that, like I have been, you know, like I have discussed, is expand that across the platform including clinicians, including the way we implement and use, we need to have a framework that works across and that is why we support the legislation is it calls for that, which would be in addition to what the FDA is doing with the higher-risk products.

Mr. BILIRAKIS. Thank you, I appreciate that. Mr. Lemnios, IBM has proposed that Watson, your supercomputer, could provide medical assistance to doctors. That is very exciting. It has the ability to review medical records, the latest in medical research, and provide recommendations or options to physicians during the diagnosis process. Would this be regulated like a medical device by the FDA in your opinion?

Mr. LEMNIOS. Well, Congressman, I can't comment on Watson as a particular product. The discussion here I think is a much bigger issue than that, and that is really about how decision support software would be regulated. And I will come back to the comments that I made earlier. I think in framing the arguments, in framing how this regulation could be structured, the distinction between whether that software is provided to the patient, or the clinician is a key one; the distinction of whether that software is used to support a decision, or to make a decision, is a clear one; and the

distinction of whether that is—whether the result of that software, the conclusions are interpreted by an individual or interpreted by a clinician is a key thing. I think those are the key, as we view it, those are the key structural elements of how to think about this. And I think the bill clearly outlines that.

Now, Watson is a technology that we are developing. We are training it. We are training it in many fields. It is in the financial sector. We are training it in the medical community. We have other areas that we will train systems like that, but I will simply tell you that the field of analytics, and the field of cognitive computing, where humans interact with data in a very natural way, that field is exploding. We see that across the VC community. We see that in other areas. And I think that will be a key element of this field going forward.

Mr. BILIRAKIS. OK, if it were regulated by the FDA, why don't you tell me, maybe you can elaborate a little bit. What kind of implications would that have? Would it raise the cost of the computer system? Would it make it slower to provide updates and improve the system?

Mr. LEMNIOS. So updates, updates on any software is a key cost issue, it is a risk issue, and it is a delivery timeline issue. I mean, we really need to see the clarity and the reason we support the bill is because we need clarity in this space.

Mr. BILIRAKIS. Thank you very much. I appreciate it. I yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman. That concludes the questions of the members here. We have two hearings going on at the same time, so I am sure some of the Members will have follow-up questions. We will send them to you. We ask that you please respond promptly, if you would. This is very, very important hearing. Thank you very much for the information, for coming today. I remind the members they have 10 business days to submit questions for the record, and members should submit those questions by the close of business on Thursday, December 5th.

Without objection, this subcommittee is adjourned.

[Whereupon, at 12:25 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Mr. Chairman, thank you for holding today's hearing on the federal regulation of mobile medical apps, software, and other health technologies as medical devices. We began this work last Congress as part of the enactment of the Food and Drug Administration Safety and Innovation Act. Innovation in this sphere must be protected, which is why we included a provision in the law on the regulation of these technologies, including medical apps.

In March, three Energy and Commerce subcommittees, including Health, held hearings on this important topic. At the hearings, we heard from a broad spectrum of witnesses, including a patient group and the Food and Drug Administration. The witnesses believed that these technologies have the potential to transform health care and help millions of patients, adding that in order to continue that progress, patients, doctors, innovators, and Congress must work together to ensure that any regulation of health information technologies protects innovation and patients.

In recent months, the FDA has taken significant action in this area. The FDA's decision to step in and regulate some of these technologies—by their own admission not all but some—is something I think most people view positively. The issue for this committee is how the FDA seeks to regulate in this space and what that means to patients and innovators both now and in the future.

I commend the FDA for its recognition that it needed to act in this space. However, I also recognize that the FDA today is ill-equipped with its current regulatory tools to manage such an undertaking. Therefore, I promise to work with the FDA to modernize these tools and regulations moving forward.

Vice-Chairman Blackburn, along with a bipartisan group of colleagues from this committee, has put forward one such proposal. It would give the FDA new and updated tools to regulate medical apps and other technology as software rather than as medical devices. It is my hope that FDA takes this offer of support seriously and will commit to working with this committee on the bipartisan, commonsense proposal we will examine today.

PREPARED STATEMENT OF HON. LOIS CAPPS

I think the evolution of medical apps-and the important balance that must be struck between patient safety and encouraging innovation. And clearly any regulatory framework must be clear and predictable for all the parties involved and resources targeted on only those products that provide risk, while allowing for the flexibility of new technologies that we have not yet dreamed of.

The FDA guidance put out to date strikes this balance and I am eager to see the health IT regulatory strategy report when it is released. I also appreciate my colleagues working on the SOFTWARE Act to keep us focused on this important issue. I hope today's hearing-and the forthcoming report-can be used to further inform that legislation before we move to any sort of markup here in committee.

I also encourage the Chairman to look at complementary legislation-the Medical Checklist Act-that Mr. Holt and I have introduced again this Congress. Checklists-whether on paper or, increasingly, included in medical apps or electronic health records are simple, yet effective ways to reduce medical errors and improve patient outcomes, and I would appreciate the opportunity to have that discussion here on the subcommittee at a future hearing.

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athenahealth

October 29, 2013

The Honorable Marsha Blackburn
US House of Representatives
217 Cannon House Office Building
Washington, DC 20515

The Honorable Phil Gingrey
US House of Representatives
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The Honorable G.K. Butterfield
US House of Representatives
2305 Rayburn House Office Building
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The Honorable Gene Green
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The Honorable Diana DeGette
US House of Representatives
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The Honorable Greg Walden
US House of Representatives
2182 Rayburn House Office Building
Washington, DC 20515

Dear Representatives,

athenahealth commends your bipartisan collaboration in the introduction of the Software Oversight for Technology Which Advances Regulatory Efficiency (SOFTWARE) Act of 2013. This legislation provides much-needed clarity regarding the oversight of various types of health information technology (health IT).

As many of you know, athenahealth provides electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices, working with a network of over 40,000 healthcare professionals in nearly every state. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our cloud platform affords to us and our clients a significant advantage over traditional, static software-based health IT products as we work to realize our company vision of a national information backbone enabling healthcare to work as it should. Our client's successes, exemplified by a Meaningful Use attestation rate more than double the national average, underscore the very real potential of health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

Consistent with the clear intent of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) and the approach laid out in a recent multi-stakeholder effort led by the Bipartisan Policy Center, ***An Oversight Framework for Patient Safety in Health Information Technology***, the SOFTWARE Act appropriately identifies three categories of health IT according to relative risk (medical software, clinical software, and health software) and provides the basis for a new risk-based regulatory framework for clinical software and health software that encourages innovation, increases patient safety, and reduces regulatory burden.

It is imperative that any oversight framework for health IT distinguishes technologies that present real risks to patients from those that do not present such risks. A rational framework will protect patients while preserving and protecting the ability of industry leaders like athenahealth to innovate and improve our services, providing myriad benefits—including safety benefits—to care providers and their patients.

HEALTHCARE
LEADERSHIP
COUNCIL

November 15, 2013

The Honorable Marsha W. Blackburn
U.S. House of Representatives
217 Cannon House Office Building
Washington, DC 20515-4207

The Honorable Diana DeGette
U.S. House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515-0601

Dear Representatives Blackburn and DeGette:

The Healthcare Leadership Council (HLC) applauds your recent efforts to drive innovation and ensure patient safety through the *Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act* (H.R. 3033). HLC members recognize the need for regulatory clarity regarding mobile medical applications, clinical decision support tools, electronic health records, and other health care related software. We are pleased to see a bipartisan approach to ensuring continued advances in patient safety and care quality through new technologies and products.

There is universal acceptance that all of those involved in healthcare need to find ways to achieve better outcomes, advance wellness, and contain costs. One avenue toward this progress is the hugely successful innovation currently underway in health information technology. Our members are making real progress in keeping people healthy, successfully combating chronic disease, improving patient outcomes, and maintaining affordability through new ideas, new inventions, and new discoveries.

We appreciate that your effort builds upon the existing work of the multi-stakeholder Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup, as well as the respected research of the Institute of Medicine, and the expertise of the Food and Drug Administration (FDA). No organization has more experience ensuring that medical devices are safe for patients than the FDA, and we acknowledge the importance of their expertise as we consider the best approaches for new technologies. We also understand and support the continued collection of input and refinements from other stakeholders as this groundbreaking legislation moves forward.

As a collaborative group of CEOs from all disciplines of American healthcare, HLC members support a continued focus on ensuring all perspectives are acknowledged as Congress considers this important issue. HLC and its members stand ready to work with you and your colleagues on both sides of the aisle to ensure that any changes drive continued innovation that increases value, improves quality, and advances patient safety.

Sincerely,

Mary R. Grealy
President

November 6, 2013

The Honorable Marsha Blackburn
217 Cannon House Office Building
Washington, DC 20515

Dear Congressman Blackburn:

The Health IT Now Coalition supports your efforts to advance legislation, H.R. 3303, the SOFTWARE Act that would clarify the regulation of medical device and health information technology software. Introducing the bill is an important first step in updating the regulatory framework for new health information technologies. We look forward to working with you to refine the bill as it moves through the legislative process.

Health IT Now is a coalition of organizations that promotes the adoption and use of health information technology (health IT) to lower costs and improve quality, safety and outcomes. Our membership is diverse; it includes healthcare providers, employers, patient advocates, and insurers.

Medical devices have made a significant impact on patient's health and have changed the way patients are treated and healed. These devices are typically discrete machines, with singular and well-defined purposes. Health IT, however, is increasingly used for multiple, novel purposes, and often in a networked environment and in ways developers had not even conceived when the software was written. This creativity is allowing patients, providers and payers to leverage technology to enhance care-coordination and management strategies that improve health outcomes and lower costs. An emerging strategy is the integrated use of mobile medical apps by clinicians and patients with electronic health records and personal health records.

Your bill would refine the types of software the Food and Drug Administration should ensure are safe and effective for use, while ensuring that clinical and health software systems fall outside the FDA review and approval process. We believe this clarity may be helpful in fostering innovation by better defining the rules of the regulatory approval process.

This is why we support your effort to cultivate a dialogue between Congress and the Administration, and to solicit input from effected stakeholders. We believe we should all work together to reform the device approval process to promote innovation and patient safety. We look forward to working with you as the legislation is refined and moves through the Congressional process.

Sincerely,

Joel C. White
Executive Director

Peter B. Davidson
Senior Vice President
Federal Government Relations

verizon

1300 I Street, NW, Suite 400 West
Washington, DC 20005

Phone: 202-515-2512
peter.b.davidson@verizon.com

November 12, 2013

The Honorable Marsha Blackburn
217 Cannon House Office Building
Washington, DC 20515

The Honorable Phil Gingrey
442 Cannon House Office Building
Washington, DC 20515

The Honorable G. K. Butterfield
2305 Rayburn HOB
Washington, DC 20515

The Honorable Gene Green
2470 Rayburn HOB
Washington, DC 20515

The Honorable Diana DeGette
2368 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
2182 Rayburn House Office Building
Washington, DC 20515

Dear Representatives:

Verizon is encouraged by and supports your efforts to provide clarity around the regulation of medical devices and health information technology. Verizon believes patient safety is critical and should be the driving force behind any federal legislation. The SOFTWARE Act (HR 3303) reflects this and is a positive step towards providing certainty for millions of application developers, device makers and entrepreneurs looking to enter this dynamic market place. More importantly this Act would help speed the development of innovative technology to ultimately drive better outcomes for patients.

Verizon, through its health care practice group, offers a comprehensive portfolio of managed IT and consulting services for the health care industry. As a technology solutions provider, Verizon understands first-hand the tremendous opportunities for improvements in health care that result from innovation in information technology. Innovations in technology are enabling greater access to care, reducing costs and improving health outcomes for millions of patients across the country.

However, an outmoded regulatory structure threatens the improvements that technology can bring to the delivery, cost and access of health care. Your bipartisan legislation will provide clarity on the types of software that the Food and Drug Administration should regulate while making sure that information management systems fall outside the FDA review and approval process. This clarification will provide more certainty for the FDA, device manufacturers and entrepreneurs to know what is within the FDA's purview and what is not. We believe your bill is a step in the right direction for addressing the gaps in existing law.

We thank you for your leadership on this important issue and look forward to working with you and your colleagues on ensuring that a proper regulatory framework is in place that fosters innovation and promotes access to potentially life-saving technologies.

Sincerely,

Application Developers Alliance

November 18, 2013

The Honorable Marsha Blackburn
Member (R-TN)
House of Representatives
217 Cannon House Office Building
Washington, D.C. 20515

Re: H.R. 3303 - Sensible Oversight for Technology, which Enhances Regulatory Efficiency (SOFTWARE) Act

Dear Representative Blackburn:

The Application Developers Alliance, on behalf of our more than 30,000 app developers and 150 corporate members, is pleased to express our appreciation for your introduction of H.R. 3303, the Sensible Oversight for Technology, which Enhances Regulatory Efficiency (SOFTWARE) Act. This bipartisan bill will provide additional regulatory clarity for developers of mobile medical apps.

As you know, app developers create innovative products and services that help patients, caregivers and physicians. The Food and Drug Administration (FDA) recently recognized these benefits when it issued its Final Guidance on Mobile Medical Apps. In the Guidance, the FDA clarified its tailored, risk-based approach to regulating mobile medical apps, an approach that is reflected in your legislation. The Alliance provided comments to the FDA, and was particularly pleased that the agency provides specific examples on its website of apps that it will regulate as well as those that it does not plan to regulate.

A significant benefit of your legislation is the certainty that it provides app developers, and the patients and providers that they serve. Additionally, by eliminating the application of the medical device tax to mobile medical apps, your legislation promotes innovation and investment in new apps that will benefit even more patients.

The Alliance is ready to work with you and your colleagues, and with the FDA, to promote a regulatory environment that encourages innovation and improves Americans' health. We welcome your legislation and look forward to the opportunity for hearings and its rapid consideration.

Sincerely,

Jon Potter
President

1025 F St, NW, Ste 720 | Washington, DC | 20004
appdevelopersalliance.org

Fostering Innovation In Health IT

IBM Position

Health IT has great promise to tremendously improve the quality, cost-effectiveness, and patient experience of care. IBM strongly supports the bi-partisan Blackburn-DeGette SOFTWARE Act to foster technological innovation by creating regulatory clarity.

We encourage you to co-sponsor H.R. 3303.

H.R. 3303 – The SOFTWARE Act

The Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act clarifies the statute of the FDA to focus regulation on high-risk "medical" software and removes low-risk "clinical" and "health" software from FDA's purview.

- Medical software is intended to treat or cure disease without the involvement of a clinician. Software in pacemakers and insulin pumps are examples.
- Clinical software does not directly impact patient care. It is intended to help physicians analyze data as they determine how to treat the patient. IBM Watson is an example.
- Health software refers to administrative tools that gather data, such as calorie counters.

It also calls for Congress and the Administration to establish a risk based framework for the later two groups.

Bill Benefits

- Encourages the continued development of evidence-based technologies that help doctors draw on far more evidence than any of them can possibly access on their own.
- Focuses the FDA's regulatory energies to software and devices that directly affect patients, without interfering with doctors' ability to access evidence-based insights.
  - All software is not the same; there should not be a one size fits all approach.
  - Current FDA regulatory framework is decades old; built for discrete devices manufactured at a single site, physically shipped to distributors/users, modified relatively infrequently, and often not interacting with other devices.
- Ensures that U.S. consumers have access to the most innovative, individualized, evidence supported medicine.

Health of Our Nation at Risk – Act Today

- Healthcare is a data rich but innovation poor environment.
  - Every 5 years, medical information doubles, but 81% of physicians spend less than 5 hours a week reading medical journals.
  - Primary care physicians spend an average of 10.7-18.7 minutes face-to-face with each patient per visit.
  - An estimated 15% of diagnoses are inaccurate or incomplete.
- IBM Watson's advanced analytics combined with cognitive computing and natural language processing can help doctors efficiently access and make use of all this data.
- Congress has the prerogative to – and should – act to legislatively clarify the health IT environment. We need the benefits of innovations in health IT, now.

July 16, 2013

The Honorable Marsha Blackburn
217 Cannon House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
2182 Rayburn House Office Building
Washington, D. C. 20515

The Honorable Phil Gingrey
442 Cannon House Office Building
Washington, D.C. 20515

The Honorable Gene Green
2470 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
2368 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressmen Blackburn, Gingrey, Walden, Green and Congresswoman DeGette,

On behalf of the Advanced Medical Technology Association (AdvaMed), thank you for the opportunity to provide comments on the draft legislation related to regulation of health information technology (IT), software, and medical health technology. We understand that the draft was put forward with a goal to solicit feedback from stakeholders, and we appreciate the opportunity to comment.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have less than $30 million in sales annually.

We appreciate your interest in the topic of regulation of health information technology. As you know, this area of technology is undergoing tremendous growth, and it is important to ensure that patient safety remains our highest priority, while still encouraging innovation.

To that end, AdvaMed believes that the following four broad principles are critical for an effective effort to regulate health IT:

1. **Regulation of either software or health IT (including software) should be platform agnostic.** By "platform agnostic" we mean that neither the platform used to run health IT, nor any IT hardware that is part of the health IT, should determine whether or how it is regulated. Additionally, if health IT is regulated, the platform used to run health IT should not determine which agency regulates it.

2. **If a product fits the current definition of a medical device, it should be regulated as a medical device.** The current test for whether a product falls under the FDA medical devices regulatory system is whether it meets the Federal Food, Drug & Cosmetic Act's definition of a

medical device. 1 We believe that health IT should be handled similarly to other FDA-regulated medical devices. If it meets that definition, it should be regulated using the same risk classification and safety and efficacy evaluation as any other medical device. We also recommend avoiding any overlap of regulation by the Office of the National Coordinator for Health Information Technology (ONC) or others.

3. **Where appropriate, regulating agencies should collaborate.** When aspects of the product could create overlapping jurisdiction (such as health IT that includes, controls, or otherwise interacts with wireless information transmission), FCC should play an appropriate coordinating role with FDA. Where multiple agencies focus on different products or different aspects of the same product, they should reference the same or similar regulatory processes so that a company's products subject to multiple agencies can use the same process to meet requirements.

4. **Regulation should harmonize with well-established international standards.** Historically, a leading inhibitor of medical device innovation has been the lack of global harmonization of regulatory requirements. This lack of global regulatory harmonization may force country-specific verification and validation activities and lifecycle management decisions, which is both costly and complex. This cost and complexity can easily stifle innovation. Building a domestic health IT regulatory environment upon well-accepted, international consensus standards and technical reports, (e.g., ISO 14971, IEC 62304, and IEC/TR 80002-1), should lead to a regulatory environment that protects the public from unnecessary risks and encourages innovation.

We believe that these principles, if implemented, will ensure a well-understood and effective means for regulating products that meet the legal definition of a medical device, while maintaining patient safety as the primary priority.

Again, thank you for the opportunity to provide comments, and we would welcome the opportunity to discuss these issues further.

Sincerely,

JC Scott
Senior Executive Vice President, Government Affairs
AdvaMed

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[1] A device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

December 16, 2013

Mr. Zachary Lemnios
Vice President, Research Strategy
IBM
600 14th Street, N.W., Suite 300
Washington, D.C. 20005

Dear Mr. Lemnios:

Thank you for appearing before the Subcommittee on Health on Tuesday, November 19, 2013, to testify at the hearing entitled "Examining Federal Regulation of Mobile Medical Apps and Other Health Software."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your response to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, January 8, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Questions for the Record Response

The Honorable Zachary J. Lemnios
Vice President, Research Strategy
IBM Research

1. The Honorable Lois Capps

2. **I appreciate hearing the impressive innovations you are partnering on with providers across the nation. Would you expand on how medical apps and electronic health records can help patients be more active in their own care and treatment decisions?**

   Thank you. I think this is a critical opportunity for patients to be more engaged in their care and raise health literacy.

3. With healthcare costs predicted to rise over 2 trillion dollars (and over 20% of the nation's GDP), we need to better accelerate innovations in health IT to improve the cost-effectiveness, quality, and access to care. We also need to bring technologies to market that enable patients to be more active in their own care and treatment decisions.

   Innovations in health IT will give patients greater access to their own personal health records in language and context patients can understand for better provider-patient engagement and results. For example, IBM is collaborating with UNC Health Care to "translate" clinical data from EMRs and medical notes into a user-friendly format so that patients can better understand their health information and participate in their care management plan.

   All this data -- personal activity tracking data, lab results, EMRs, etc. -- is expected to create an unprecedented, and actionable, view of a patient's health. Medical applications can also help healthcare providers gain practical access to this data in near real time, which may improve the care that they can provide. Further, this access can also help patients and their care network adjust more quickly based upon a faster data feedback loop.

   Most everyone agrees that the current regulatory framework for medical devices is out-of-date and an obstacle to commercializing the latest health IT, including advancements in mobile medical applications. FDA is attempting to address this issue with non-binding guidance documents. We believe that this approach does not establish sufficient regulatory clarity and certainty. Congress can help by establishing a statutory framework that reliably fosters patient-centric care innovations and facilitates bringing these applications to market.

   Legislation that establishes updated regulatory clarity will help foster technological innovation for the medical world to truly partner with their patients and be part of a patient's life flow, which is critically needed to drive quality care, lower costs, and improve outcomes.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 226–3641

December 16, 2013

Dr. J. Leonard Lichtenfeld
Deputy Chief Medical Officer
American Cancer Society, Inc.
250 Williams Street
Atlanta, GA 30303

Dear Dr. Lichtenfeld:

Thank you for appearing before the Subcommittee on Health on Tuesday, November 19, 2013, to testify at the hearing entitled "Examining Federal Regulation of Mobile Medical Apps and Other Health Software."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your response to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

January 8, 2014

The Honorable Joseph R. Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Representative Pitts,

Per your request, below you will find my response to the question for the record posed by Representative Capps. If you have any further questions, please do not hesitate to contact me.

Regards,

J. Leonard Lichtenfeld, MD, MACP
Deputy Chief Medical Officer
American Cancer Society, Inc.

Question from Rep. Lois Capps:

> ***Research has shown that for cancer patients and survivors, have [sic] a care plan that is developed by the provider and the patient as a team is key to better health outcomes, patient satisfaction, and can lead to lower health care costs. That is why I authored the Planning Activity for Cancer Treatment (PACT) Act to help make these plans the standard of care.***
>
> ***How do you see the medical apps as affecting cancer care?***
>
> ***I look forward to seeing how these medical technologies can help make care planning, especially for cancer care, a reality for all who want to be more engaged in their own care.***

Answer:
Mobile applications and innovative software help us organize and plan our professional and personal lives, and they offer the same promise when it comes to a cancer patient's journey from diagnosis through treatment and into survivorship. Applications can be used by patients and/or physicians to make data transactions easier, or they can actively suggest or facilitate decisions and evaluations.

The treatment of cancer typically involves the interaction of numerous healthcare providers and it is important for all of the providers to have the same access to all of a patient's information including the patient's own treatment goals. For a patient, navigation through the multiple providers participating in the patient's care can be complex, especially considering the added physical and emotional stresses created by the disease itself. The use of medical software, such as electronic medical records, can help ensure consistency, accuracy, and availability of information used by both patients and providers alike.

In addition to better organizing clinical data, mobile applications can allow patients to generate their own data. This could include not only their treatment goals but real-time outcomes as well, like pain, nausea, functionality and fatigue, which often go unreported and are difficult for providers to accurately evaluate. These outcomes, often referred to as patient-reported outcomes (PROs), are used to monitor and adjust treatment to ensure a patient's treatment goals are met.

Lastly, research is constantly resulting in new diagnostics and therapies available to treat cancer. Software applications tied into appropriate data sources can aid physicians and patients in selecting the most appropriate options to diagnose and treat specific cancers.

A sample listing of cancer-related software applications has been compiled by the eHealth Initiative and can be found at: http://www.ehidc.org/resource-center/directories/hit-cancer-resource-guide

In short, medical software applications have the potential to flatten the information landscape, providing everyone with the same accurate and up-to-date information, and they also have the potential to better organize, plan and administer treatment. While this potential is enormous, it will only be realized if the applications that are created adhere to evidence, are kept up to date, and accurately perform the functions that they are intended to. Use of applications that do not work correctly or contain outdated information could be worse for patients than not having such applications at all. Like any tool used to fight cancer, the value of software applications will depend on proper design and use.